Safety and efficacy of APSA PHYTAFEED® 20,000 GR/L (6-phytase) as a feed additive for piglets (suckling and weaned) and growing minor porcine 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, Jordi 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 for piglets and growing minor porcine 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 piglets 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 Panel concluded that the additive is safe for piglets (suckling and weaned) and for growing minor porcine species at the recommended enzyme activity of 250 U/kg feed with a wide margin of safety. The applicant submitted three efficacy trials to support the efficacy of the additive. In the trials, the apparent faecal digestibility 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 piglets (suckling and weaned) and for growing minor porcine species at an enzyme activity of 1,000 U/kg feed.

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Correspondence: feedap@efsa.europa.eu
Panel members: Giovanna Azimonti, Vasileios Bampidis, 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 and Ruud Woutersen.

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Note: Relevant information or parts of this scientific output have been blackened in accordance with the European Commission decision on the confidentiality requests formulated by the applicant. A previous, provisional version of this output which had been made publicly available pending the adoption of the decision has been replaced by this version. The full output has been shared with the European Commission, EU Member States and the applicant.

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Table of contents

Abstract .................................................................................................................................................... 1
1. Introduction .................................................................................................................................. 4
   1.1. Background and Terms of Reference ....................................................................................... 4
   1.2. Additional information .............................................................................................................. 4
2. Data and methodologies ................................................................................................................ 4
   2.1. Data ............................................................................................................................................. 4
   2.2. Methodologies ............................................................................................................................... 4
3. Assessment ................................................................................................................................... 5
   3.1. Characterisation ............................................................................................................................ 5
   3.2. Safety .......................................................................................................................................... 5
       3.2.1. Safety for piglets ....................................................................................................................... 6
       3.2.1.1. Conclusions on the safety for the target species ................................................................. 7
3.4. Efficacy for piglets .......................................................................................................................... 8
4. Conclusions ................................................................................................................................... 8
Documentation as provided to EFSA/Chronology .................................................................................. 9
References ........................................................................................................................................... 9
Abbreviations ...................................................................................................................................... 9
1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/20031 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® 20,000 GR/L (6-phytase), when used as a feed additive for piglets (suckling and weaned) and minor growing porcine 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® 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® 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 dossier3 in support of the authorisation request for the use of APSA PHYTAFEED® 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 to deliver the present output.

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® 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® 20,000 GR/L (6-phytase) is in line with the principles laid down in Regulation (EC) No 429/20085 and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Pane, 2017) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

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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-2019-0020.
4 The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/fin_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 PHYTAFEED® 20,000 GR/L contains 6-phytase activity (EC 3.1.3.26; phytase) and is intended to be used in feed for piglets (suckling and weaned) and growing minor porcine 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 *Komagataella 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 PHYTAFEED® 20,000 GR and a liquid one APSA PHYTAFEED® 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 piglets.

*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 applicant has provided new data on the stability and the capacity to homogeneously distribute of the additive when added to feed for piglets. 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) in order to study the effect of processing. Recovery values after granulation showed no modifications of the initial enzyme activity. Samples of the mash and granulated 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 feeds used in the stability study. Samples of the mash feeds showed a coefficient of variation (CV) of 8% for both the solid and liquid formulations and the samples of the pelleted feed showed a CV of 11%.

The additive is to be used in feed for suckling and weaned piglets and in growing minor porcine 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 consumers, for the user and for the environment have been previously assessed (EFSA FEEDAP Panel, 2019). The Panel concluded that the use of the product as a feed additive raises no concerns for consumer safety and for the environment. Regarding the safety for the user, the Panel concluded that additive is not irritant for skin or eye and it is not a dermal sensitiser, but it is considered a potential respiratory sensitiser.

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

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6 Technical dossier/Section II/Annex II.2.1.2.
7 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.
8 Technical dossier/Supplementary information September 2019/Annex II.2.1.2.7.
9 Technical dossier/Section II/Annex II.4.1.3.1 and II.4.1.3.2.
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.

3.2.1. Safety for piglets

A tolerance trial in weaned piglets was submitted. A total of 144 weaned piglets (male and female, (Duroc × Landrace) × Piétrain) were distributed in 36 pens in groups of 4 animals (mixed sexes). The first seven days after weaning the animals were in an adaptation period and received a common diet (see positive control). Then after, the experimental period started the animals (body weight 9 kg) received one of the six experimental diets (representing 6 replicates per treatment). The experimental diets were obtained from two basal diets (starter and grower) based on maize and soya bean meal (total phosphorus 4.2 and 3.9 g/kg, total calcium 8.0 and 7.1 g/kg, respectively) which were either not supplemented (control) or supplemented with APSA PHYTAFEED® 20,000 GR to provide 250 (1 × recommended level), 500 (2 ×), 1,000 (4 ×) or 100,000 (400 ×) U per kg feed (confirmed by analysis). A positive control diet was also included (total phosphorus 6.7 and 6.2 g/kg, total calcium 8.0 and 7.1 g/kg, respectively). Diets were offered on ad libitum basis in pelleted form for 42 days. Mortality and health status were checked daily. Animals were individually weighed on days 0, 14 and 42 under study, feed intake was registered per pen and feed to gain ratio calculated. Blood samples were obtained in 12 piglets on day 0 (6 males and 6 females) and 42 (random selection per treatment not specified how many per pen) for haematology and clinical chemistry analysis. An analysis of variance (ANOVA) was done with the performance data (pen basis) and considering the treatment as the effect. Group means were compared with Tukey test. Significance level was set at 0.05.

No piglets died during the study. The results on the feed intake, body weight and feed to gain ratio are presented in Table 1. The results showed a reduced growth of the piglets in the control diet compared to the other groups. The addition of the phytase restored, as compared to the positive control, the growth of the piglets from 1,000 U/kg feed. The performance registered in the control group does not allow to use it as a control to identify any impairment of the performance in animals receiving the phytase. However, the data from the groups receiving the phytase did not show a negative dose related trend with increasing levels of the phytase in the performance; in fact, significant improvements on the performance were seen with increasing levels of the phytase, from the level of 250 U/kg feed.

These improvements resulted in no differences in the final body weight compared to the positive control but only when the supplementation reached 1,000 U/kg feed or higher.

The results in the blood parameters showed effects on the mean corpuscular volume, haematocrit, haemoglobin, erythrocytes, alkaline phosphatase and alanine aminotransferase. However, most of the effects did not show a dose response, the only one that showed a clear pattern was the alkaline phosphatase which was highest in the negative control 235.8 (U/L) compared to the diets supplemented with phytase from 500 U/kg onwards and the positive control. However, this effect can be related to the availability of phosphorus in the animals.

Table 1: Effect of APSA PHYTAFEED® 20,000 on the performance of weaned piglets

| Groups (U/kg feed) | Daily feed intake (g) | Final body weight (Kg) | Feed to gain ratio |
|--------------------|-----------------------|------------------------|-------------------|
| 0                  | 595                   | 23.0c                  | 1.80a             |
| 250                | 671                   | 25.3b                  | 1.74ab            |
| 500                | 647                   | 25.5b                  | 1.65ab            |
| 1,000              | 644                   | 26.4ab                 | 1.56b             |
| 100,000            | 681                   | 27.3ab                 | 1.57ab            |
| Positive control   | 685                   | 27.2a                  | 1.58ab            |

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

The parameters measured included: mean corpuscular haemoglobin concentration, mean corpuscular haemoglobin mean corpuscular volume, haematocrit, haemoglobin, erythrocytes, platelets, leukocytes, eosinophils, basophils, lymphocytes, monocytes, segmented neutrophils and band neutrophils.

Parameters measured included: alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, gamma glutamine transpeptidase, total proteins, albumin and Uric acid.
A subchronic oral toxicity study in rats, formerly assessed by the FEEDAP Panel (EFSA FEEDAP Panel, 2019), was provided. The results of that study indicate a no-observed-adverse-effect-level (NOAEL) of 119,228 U/kg body weight in rats. Using this NOAEL, and applying the procedure detailed in the guidance on the safety for the target species (EFSA FEEDAP Panel, 2017), the maximum safe level for piglets in feed is calculated to be 23,846 U/kg feed. This value is approximately 95 times higher than the proposed use level and would support the results of the tolerance study.

### 3.2.1.1. Conclusions on the safety for the target species

The FEEDAP Panel concludes that APSA PHYTAFEED® 20,000 GR/L is safe for weaned piglets at the recommended level of 250 U/kg feed with a wide margin of safety. This conclusion is extended to suckling piglets. Considering the wide margin of safety the Panel extrapolates the conclusion to growing minor porcine species.

### 3.3. Efficacy for piglets

Two digestibility trials that included bone measurements and a performance trial were submitted for the assessment.

The two digestibility trials were conducted in the same trial site and followed the same trial design. In the two trials, male weaned piglets (Duroc × Landrace) × Yorkshire were subject to an adaptation period of 7 days after weaning and then after were individually caged and one of the five treatments were allocated. In trial 1, there were a total of 7 piglets per treatment and in trial 2 a total of 8. Basal diets (pre-starter and starter) based on maize and soya bean meal were either not supplemented (control) or supplemented with APSA PHYTAFEED® 20,000 GR to provide 250, 500 or 1,000 U/kg feed. The enzyme activities were confirmed by analysis. In the two trials, a positive control diet with higher content of phosphorus was also considered. Diets were offered in mash form for 24 or 21 days, respectively, and the ones given in the starter phase (from day 17 in trial 1 or from day 14 in trial 2) contained an external marker (titanium dioxide in trial 1 and insoluble ash in trial 2).

Mortality and health status of the piglets were checked every day. Animals were weighed and feed intake was measured throughout the study period. Spot samples of faeces were collected in days 22–24 in trial 1 and days 15–19 in trial 2 (no adaptation period to the diet). Feed and the faeces collected were analysed for the phosphorus content and external marker in order to study the digestibility. On the last day of the study, all animals were killed and the os metacarpale was collected from each animal to analyse it for ash and phosphorus content. 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 performance trial is the tolerance trial described in Section 3.2.1. In that trial, the performance of the piglets was measured and measurements on the digestibility of phosphorus and bone content of minerals were also done. Faecal samples were collected on days 19-21 under study. The diets contained titanium dioxide as an external marker and faecal samples were collected daily from the pens. Feed and excreta samples were analysed for the marker, ash, dry matter, calcium and phosphorus to determine the utilisation. Os metacarpale from one piglet per pen was collected at the end of the study (random selection) and the bones were analysed for ash content.

The results of the balance trials are presented in Table 2 and the performance parameters of trial 3 in Table 1 (see Section 3.2.1). The piglets that received the phytase showed higher faecal apparent digestibility of phosphorus in the three trials compared to the control group, from the enzyme activity of 250 U/kg feed in trials 1 and 2 and from 1,000 U/kg feed in trial 3. The bone content of ash and/or phosphorus was higher in the piglets receiving the phytase from 250 U/kg feed in trial 2,500 U/kg feed in trial 1 and from 1,000 U/kg feed in trial 3. The Panel considers that the performance data in the tolerance trial can only support the efficacy of the additive due to the performance of the piglets. The results on the utilization of phosphorus show that the additive has a potential to be efficacious as a zootechnical additive in weaned piglets at the dose of 1,000 U/kg feed.

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13 Technical dossier/Section III/Annex III.2.2.3.
14 Technical dossier/Section IV/Annex IV.2.1 and Annex IV.2.2 and supplementary information September 2019/Annexes IV.2.1_updated and IV.2.2_updated.
The FEEDAP Panel concludes that APSA PHYTAFEED® 20,000 GR/L is efficacious as a zootechnical additive for weaned piglets at 1,000 U/kg feed. This conclusion is extended to suckling piglets. Considering that the mode of action of the phytases is well known and it is reasonably assumed to be the same among porcine species, the Panel extrapolates the conclusion on the efficacy to growing minor porcine species.

### 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 and Good Manufacturing Practice.

### 4. Conclusions

APSA PHYTAFEED® 20,000 GR/L is safe for piglets (suckling and weaned) and for growing minor porcine 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® 20,000 GR/L in piglets and growing minor porcine species. The additive is not a skin or eye irritant, and it is not a dermal sensitizer but it should be considered a respiratory sensitizer.

The FEEDAP Panel concludes that APSA PHYTAFEED® 20,000 GR/L is efficacious for piglets (suckling and weaned) and for growing minor porcine species at an enzyme activity of 1,000 U/kg feed.

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**Table 2:** Effect of APSA PHYTAFEED® 20,000 on the apparent faecal digestibility of phosphorus and os metacarpale bone mineralisation

| Trial | Phytase (Units/kg feed) | Total P – Ca (g/kg feed) | Faecal apparent digestibility of phosphorus (%) | Bone content (%) |
|-------|-------------------------|--------------------------|-----------------------------------------------|------------------|
|       |                         |                          | Ash                                           | Phosphorus       |
| 1     | 0                       | 3.0–3.4                  | 41.6<sup>a</sup>                              | 37.4            |
|       | 250                     | 3.0–3.4                  | 63.8<sup>b</sup>                              | 41.1            |
|       | 500                     | 3.0–3.4                  | 74.9<sup>c</sup>                              | 42.5            |
|       | 1,000                   | 3.0–3.4                  | 77.2<sup>a</sup>                              | 42.4            |
| Positive control | 3.6–4.5                |                          | 62.9<sup>b</sup>                              | 42.2            |
| 2     | 0                       | 3.7–4.8                  | 50.5<sup>a</sup>                              | 37.8<sup>b</sup> |
|       | 250                     | 3.7–4.8                  | 65.7<sup>ab</sup>                             | 42.9<sup>a</sup> |
|       | 500                     | 3.7–4.8                  | 73.9<sup>a</sup>                              | 42.8<sup>a</sup> |
|       | 1,000                   | 3.7–4.8                  | 77.0<sup>a</sup>                              | 42.6<sup>a</sup> |
| Positive control | 5.4–6.9                |                          | 61.7<sup>bc</sup>                             | 41.4<sup>a</sup> |
| 3     | 0                       | 3.9–7.1                  | 22.9<sup>c</sup>                              | 32.6<sup>c</sup> |
|       | 250                     | 3.9–7.1                  | 33.0<sup>c</sup>                              | 36.2<sup>c</sup> |
|       | 500                     | 3.9–7.1                  | 43.6<sup>bc</sup>                             | 37.2<sup>bc</sup> |
|       | 1,000                   | 3.9–7.1                  | 55.0<sup>ab</sup>                             | 41.8<sup>ab</sup> |
|       | 100,000                 | 3.9–7.1                  | 68.9<sup>a</sup>                              | 44.3<sup>a</sup> |
| Positive control | 6.2–7.1                |                          | 26.2<sup>c</sup>                              | 42.8<sup>a</sup> |

(1): Intended values for the diets administered during the period in which collection of faeces was done.

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

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15 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.
**APSA PHYTAFEED® 20,000 GR/L for piglets**

**Documentation as provided to EFSA/Chronology**

| Date       | Event                                                                                                                                                                                                 |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 04/03/2019 | Dossier received by EFSA. APSA PHYTAFEED® 20,000 GR/L for piglets and minor growing porcine 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                                                                                                                                      |
| 08/07/2019 | 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 and efficacy |
| 14/08/2019 | Clarification teleconference during risk assessment with the applicant according to the "EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products“                                 |
| 26/09/2019 | Reception of supplementary information from the applicant - Scientific assessment re-started                                                                                                            |
| 7/10/2019  | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment                                                                                                                                   |

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**Abbreviations**

ANCOVA 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