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Safety and efficacy of ROVABIO[®] SPIKY (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a feed additive for all major and minor poultry species

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

Abstract

ROVABIO[®] SPIKY is a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase that is authorised as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, minor poultry species for fattening and reared for laying. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) issued two opinions on this additive. Safety aspects regarding the use of this additive in feed have been previously established. The Panel concluded that the additive is safe for the consumers and the environment and that the additive is not irritant to the skin or eyes but should be considered a potential skin sensitiser and potentially harmful if inhaled. The Panel considered that these conclusions are still valid for the current application. The current application covered the use of the additive in all poultry species at the dose of 1,100 U xylanase and 760 U glucanase per kg feed. In previous assessments, the Panel concluded that the additive is safe and efficacious under the proposed conditions of use in chickens and turkeys for fattening or raised for laying/breeding and to minor poultry species for fattening or raised for laying/breeding. In order to support the safety for laying animals, the applicant provided a tolerance trial in laying hens from which the Panel concluded that the additive is safe for laying hens at the recommended dose. The safety established in laying hens is considered to apply also to breeding hens and can be extrapolated to minor poultry species for laying. Regarding the efficacy the additive increased the metabolisable energy content of the diets in one trial and the performance of the laying hens in two trials at the recommended dose. Therefore, the FEEDAP Panel concluded that the additive has the potential to be efficacious in laying hens. This conclusion applies also to breeding hens and can be extrapolated to include all minor poultry species for laying.

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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 Panel) was asked to deliver a scientific opinion on the safety and efficacy of ROVABIO® SPIKY (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a feed additive for all poultry species. This additive is available in solid and liquid forms and is prepared by combining two products of fermentation obtained from two strains of *Penicillium funiculosum* (*Talaromyces versatilis* sp. novus) (IMI 378536 and DSM 26702), one of which is non-genetically modified and the other is genetically modified.

The additive is authorised as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, minor poultry species for fattening and reared for laying. The FEEDAP Panel issued an opinion in 2014 on the safety and efficacy of ROVABIO® SPIKY (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a feed additive for chickens for fattening, chickens reared for laying and other minor poultry species (for fattening and reared for laying). This opinion considered the safety aspects of the additive regarding the consumer, the user, the environment and the genetic modification of one of the production strains. Another opinion was adopted in 2015 regarding the use of the additive as a feed additive for turkeys.

Safety aspects regarding the use of this additive in feed including the safety for the consumers, for the users and for the environment have been previously established. The Panel concluded that the additive is safe for the consumers and the environment and that the additive is not irritant to the skin or eyes but should be considered a potential skin sensitiser and potentially harmful if inhaled. The FEEDAP Panel is not aware of any new information that would lead it to reconsider the conclusions drawn previously. Moreover, the FEEDAP Panel considers that the new use would not modify any conclusion.

The current application covered the use of the additive in all poultry species at the dose of 1,100 U xylanase and 760 U glucanase per kg feed. In previous assessments, the FEEDAP Panel concluded that the additive is safe and efficacious under the proposed conditions of use in chickens and turkeys for fattening or raised for laying/breeding and to minor poultry species for fattening or raised for laying/breeding.

In order to support the safety for laying animals, the applicant provided a tolerance trial in laying hens. On the basis of the results obtained in that tolerance trial, the Panel concluded that the additive is safe at the recommended dose. In the view of the Panel, the safety established in laying hens applies also to breeding hens. Moreover and considering the wide margin of safety demonstrated, the Panel considers that the conclusion can be extrapolated to minor poultry species for laying.

The applicant submitted three efficacy studies (one short-term trial and two long-term trials) in laying hens in order to support the efficacy for laying birds at the recommended dose of 1,100 U xylanase and 760 U glucanase per kg feed. The addition of the additive at the recommended dose increased the metabolisable energy content of the diets in one trial and the performance of the hens in two trials. Therefore, the FEEDAP Panel concluded that the additive has the potential to be efficacious in laying hens at the recommended dose. The Panel considers that the efficacy established in laying hens applies also to breeding hens and that as the mode of action of xylanase and glucanase can be reasonably assumed to be the same in all avian species, the conclusions on the efficacy for laying hens can be extrapolated to include all minor poultry species for laying.

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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 Adisseo France S.A.S.² for authorisation of the product ROVABIO® SPIKY (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase), when used as a feed additive for all poultry species (category: zootechnical additive; 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 7 December 2015.

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 ROVABIO® SPIKY (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase), when used under the proposed conditions of use (see Section 3.1).

1.2. Additional information

The additive ROVABIO® SPIKY is a preparation of endo-1,4-beta-xylanase (xylanase: EC 3.2.1.8) and endo-1,3(4)-beta-glucanase (glucanase: EC 3.2.1.6) and is available in solid and liquid forms (ROVABIO® SPIKY AP and ROVABIO® SPIKY LC, respectively). This additive is prepared by combining two products of fermentation obtained from two strains of *Penicillium funiculosum* (*Talaromyces versatilis* sp. novus) (IMI 378536 and DSM 26702).

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) issued an opinion on the safety and efficacy of ROVABIO® SPIKY as a feed additive for chickens for fattening, chickens reared for laying and other minor poultry species (for fattening and reared for laying) (EFSA FEEDAP Panel, 2014). This opinion considered the safety aspects of the additive regarding the consumer, the user, the environment and the genetic modification of one of the production strains. Another opinion was adopted in 2015 regarding the use of the additive as a feed additive for turkeys (EFSA FEEDAP Panel, 2015).

The additive is authorised as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, minor poultry species for fattening and reared for laying.^{3,4}

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the use of ROVABIO® SPIKY (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a feed additive. The technical dossier was prepared

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 Adisseo France S.A.S., Immeuble Antony Parc II 10, Place du Général de Gaulle, 92160 Antony, France.

³ Commission implementing Regulation (EC) 2015/661 of 28 April 2015 concerning the authorisation of the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying (holder of the authorisation Adisseo France S.A.S.). OJ L 110, 29.4.2015, p. 1.

⁴ Commission Implementing Regulation (EC) 2015/2304 of 10 December 2015 concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702 as a feed additive for turkeys for fattening and for breeding (holder of the authorisation Adisseo France S.A.S.). OJ L 326, 11.12.2015, p. 39.

⁵ FEED dossier reference: FAD-2015-0032.

following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008⁶ and the applicable EFSA guidance documents.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.⁷

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of ROVABIO® SPIKY (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012a), Technical guidance: tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011), Technical Guidance: extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition (EFSA, 2008), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012b), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012c).

3. Assessment

The additive is authorised as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, minor poultry species for fattening and reared for laying. The current application covers the use of the additive in all poultry species. The safety and efficacy of this additive in poultry species for fattening or reared for laying/breeding has been previously established. In the current assessment, the Panel assesses the safety and efficacy of the product as a feed additive for laying/breeding birds.

3.1. Characterisation of the additive

The additive was described in full in a previous opinion (EFSA FEEDAP Panel, 2014) and no new information has been provided.

The additive ROVABIO® SPIKY is a preparation of endo-1,4-beta-xylanase (xylanase: EC 3.2.1.8) and endo-1,3(4)-beta-glucanase (glucanase: EC 3.2.1.6) and is available in solid and liquid forms (ROVABIO® SPIKY AP and ROVABIO® SPIKY LC, respectively). This additive is prepared by combining two products of fermentation obtained from two strains of *P. funiculosum* (*Talaromyces versatilis* sp. novus) (IMI 378536 and DSM 26702).

The analysis of the enzyme activities in the additive is performed following two methods: a viscosimetric-based method (viscosimetric units (U))⁸ or a method based on the colour formation of released sugars with 3,5-dinitrosalicylic acid (DNS U).⁹ Per gram of solid product, the minimum specified activity is of 22,000 U or 2,300 DNS U for xylanase activity and 15,200 U or 1,600 DNS U for glucanase activity. Per millilitre of liquid product, the minimum specified activity is of 5,500 U or 570 DNS U for xylanase activity and 3,800 U or 400 DNS U for glucanase activity.

The additive is intended to be used in feed for poultry at a recommended dose of 1,100 xylanase viscosimetric units and 760 glucanase viscosimetric units per kg feed.

3.2. Safety

Safety aspects regarding the use of this additive in feed including the safety for the consumers, for the users and for the environment have been previously established (EFSA FEEDAP Panel, 2014). The Panel concluded that there are no concerns for consumer safety and no risks for the environment are expected. The Panel also concluded that both forms of the additive are not irritant to the skin or eyes

⁶ 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.

⁷ The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2013-0030-Rovabio_Spiky.pdf

⁸ One xylanase (or beta-glucanase) viscosity unit (U) is defined as the amount of xylanase (or beta-glucanase) that hydrolyses wheat arabinoxylan (or barley beta-glucan), reducing the solution viscosity, in order to change the relative fluidity by one dimensionless unit per minute, at pH 5.5 and 30°C.

⁹ One xylanase (or beta-glucanase) DNS unit corresponds to the amount of xylanase (or beta-glucanase) which liberates from the birchwood xylan (or barley beta-glucan) 1 µmol of xylose (or glucose) per minute at 50°C and pH 4.0 (or pH 5.0).

but should be considered a potential skin sensitiser and potentially harmful if inhaled. The FEEDAP Panel is not aware of any new information that would lead it to reconsider the conclusions drawn previously. Moreover, the FEEDAP Panel considers that the new use would not modify the above conclusions.

The current application covers the use of the additive in all poultry species. In previous assessments, the FEEDAP Panel concluded based on tolerance trials in chickens and on turkeys for fattening that the additive is safe under the proposed conditions of use in chickens and turkeys for fattening or raised for laying/breeding and to minor poultry species for fattening or raised for laying/breeding. The solid and liquid forms of the additive are considered to be equivalent in terms of safety for the target species.

In order to support the safety for laying animals, the applicant provided a tolerance trial in laying hens.

3.2.1. Safety for laying hens

A total of five hundred and seventy-six 21-week-old Hy-Line-Brown laying hens were placed in enriched cages in groups of eight hens.¹⁰ The cages were allocated to three dietary treatments considering the location in the battery as a block. There were in total 24 replicates per treatment. A basal diet based on wheat, maize and soya bean meal was either not supplemented (control) or supplemented with ROVABIO® SPIKY AP to provide (xylanase/glucanase) 2,200/1,520 (2× recommended dose) or 220,000/152,000 (200×)U/kg feed (confirmed by analysis). Diets were offered *ad libitum* as mash for 56 days. Health status and mortality of the animals were monitored throughout the study. Body weight was measured at the beginning and at the end of the trial, with measurements done on a cage basis. Feed intake was monitored throughout the study every 4 weeks. All eggs produced were collected and weighed every second day. Feed to egg mass ratio was calculated per replicate and period. At the end of the study, a total of 192 eggs per treatment were evaluated for weight of eggshell, yolk, albumen, Haugh units and egg yolk colour. An ANOVA was performed on the data obtained, cage being the experimental unit, and means were compared with the Duncan's test. Differences were considered significant at $p < 0.05$.

No hens died during the experiment, health status was good and no major incidences occurred during the study. No differences between treatments were found on the feed intake (115.6, 116.3, 114 g/hen per day for control, 2× and 200×, respectively), egg production (91.8%, 93.4% and 92.5%), average egg weight (57.8, 57.8 and 57.4 g/egg), daily egg mass output (53.1, 54.0 and 53.0 g/day), or feed to egg mass ratio (2.18, 2.16 and 2.15). Body weight gain of the hens was significantly improved by the 200× diet compared to the control diet (3.1, 3.4, 3.9 g/day for control, 2× and 200×, respectively). No differences were found in the egg quality parameters measured.

Supplementation of the experimental diet with 200-fold the recommended dose did not have adverse effects on the performance of the birds.

3.2.1.1. Conclusions on the safety for laying birds

On the basis of the results obtained in the tolerance trial in laying hens, the Panel concludes that the additive is safe at the recommended dose. In the view of the Panel, the safety established in laying hens applies also to breeding hens. Moreover and considering the margin of safety demonstrated, the Panel considers that the conclusion can be extrapolated to minor poultry species for laying.

3.3. Efficacy

In previous assessments, the FEEDAP Panel evaluated the efficacy in chickens and turkeys for fattening and concluded that the additive is efficacious at 1,100 U xylanase and 760 U glucanase per kg feed. The conclusion was extended to chickens reared for laying and turkeys reared for breeding and it was extrapolated to minor poultry species for fattening or reared for laying/breeding. The solid and liquid forms of the additive are considered to be equivalent in terms of efficacy for the target species.

The applicant has submitted studies (one-short term trial and two long term trials) in laying hens, in order to support the efficacy for laying birds.

¹⁰ Technical dossier/Section III/Annex III.1.1 and Supplementary information May 2016/Annex 1.

3.3.1. Efficacy for laying hens

3.3.1.1. Short-term trial

Sixty 23-week-old Shaver 477 Brown laying hens individually caged were used.¹¹ The hens received a prestarter diet based on wheat, soya bean meal and barley for 2 weeks. Egg production was monitored during the last 10 days. At the end of week 25 and after a 2-h fasting period in the dark, 40 hens were selected (according to laying rate and body weight), individually caged and allocated to two dietary treatments, representing 20 replicates of one hen per treatment. A basal diet based on wheat, barley and soya bean meal was either not supplemented (control) or supplemented with ROVABIO® SPIKY LC to provide 1,100 U xylanase and 760 U glucanase per kg feed (confirmed by analysis). Diets were offered *ad libitum* as pellets for 14 days. After an adaptation period of 9 days, excreta were collected for 5 days. Excreta and feed were analysed in order to study the AME content of the feed. The AME values were corrected for nitrogen (AMEn). Hens were weighed at the start of the experimental period, before the collection of excreta and at the end of the collection period. Egg production was monitored daily. An ANOVA was performed on the data. Differences were considered significant at $p < 0.05$. The results are given in Table 1.

Table 1: Effect of ROVABIO® SPIKY on the apparent metabolisable energy (AME) and nitrogen-corrected AME (AMEn) content of the diets

	AME (MJ/kg dry matter)	AMEn (MJ/kg dry matter)
Control	12.05 ^b	11.72 ^b
ROVABIO® SPIKY	12.38 ^a	12.04 ^a

^{a,b}: Within one column, mean values with different superscripts are significantly different ($p < 0.05$).

No hens died during the experiment. No differences between treatments were observed in the body weight of the animals, the laying rate, the egg weight and mass, the feed intakes and feed conversion ratios. The treatment had no effect on egg quality characteristics. The AME and AMEn were improved by the treatment.

3.3.1.2. Long-term trials

In the first long-term trial, a total of six hundred and seventy-two 21-week-old Lohmann Brown laying hens were placed in enriched cages in groups of 21 hens and allocated to two dietary treatments, representing 16 replicates per treatment.¹² A basal diet based on triticale and soya bean meal was either not supplemented (control) or supplemented with ROVABIO® SPIKY AP to provide 1,100 U xylanase and 760 U glucanase per kg feed (confirmed by analysis). Diets were offered *ad libitum* in mash form for 168 days. Health status and mortality of the animals were monitored biweekly throughout the study. Body weight was measured at the beginning and at the end of the trial. Feed intake was monitored biweekly throughout the study. All eggs produced were collected and weighed. Feed to egg mass ratio was calculated. On the last week of the study, 21 eggs per cage were analysed for egg shell and albumen weight and in four eggs per cage, egg yolk colour was measured. An ANOVA was performed on the data with the cage as the experimental unit. Differences were considered significant at $p < 0.05$. The results are given in Table 2.

Table 2: Effect of ROVABIO® SPIKY on the performance of laying hens in the first long-term trial

	Daily feed intake (g)	Laying rate (%)	Egg weight (g)	Daily egg mass (g)	Feed to egg mass ratio	Mortality (%)
Control	123.5 ^a	95.4 ^b	60.4	57.6	2.14 ^a	2.98
ROVABIO® SPIKY	121.7 ^b	96.6 ^a	60.4	58.3	2.09 ^b	2.68

^{a,b}: Within one column, mean values with different superscripts are significantly different ($p < 0.05$).

¹¹ Technical dossier/Section IV/Annex IV.1.1 and Supplementary information May 2016/Annex 2.

¹² Technical dossier/Section IV/Annex IV.1.2.

Mortality was below 3% and was not affected by the treatment. No differences between treatments were observed in the body weight of the hens and in egg weight and mass. Enzyme addition at the recommended dose increased the laying rate and decreased the feed intake and the feed to egg mass ratio. No differences were found between treatments regarding the egg quality parameters measured (data not shown).

In the second trial, a total of three hundred and eighty-four 20-week-old Hy Line brown laying hens were placed in enriched cages in groups of eight hens and allocated to two dietary treatments, representing 24 replicates per treatment.¹³ A basal diet based on wheat, wheat bran and soya bean meal was either not supplemented (control) or supplemented with ROVABIO® SPIKY AP to provide 1,100 U xylanase and 760 U glucanase per kg feed (confirmed by analysis). Diets were offered *ad libitum* as mash for 196 days. Health status and mortality of the animals was monitored throughout the study. Body weight was measured at the beginning and at the end of the trial. Feed intake was monitored every 4 weeks throughout the study. All eggs produced were collected and weighed every second day and feed to egg mass ratio was calculated. On week 42 of life, eight eggs per cage were analysed for egg shell, yolk and albumen weights, albumen Haugh units and yolk colour. An ANOVA was performed on the data with the cage as the experimental unit. Differences were considered significant at $p < 0.05$. The results are given in Table 3.

Table 3: Effect of ROVABIO® SPIKY on the performance of laying hens in the second long-term trial

	Daily feed intake (g)	Laying rate (%)	Egg weight (g)	Egg mass (g/hen per day)	Feed to egg mass
Control	119.8	92.1	62.3	57.3	2.09 ^a
ROVABIO® SPIKY	118.2	92.8	62.3	57.8	2.05 ^b

^{a,b}: Within one column, mean values with different superscripts are significantly different ($p < 0.05$).

Three hens died during the study, one from the control diet and two from the treated group. No significant differences between treatments were observed in the body weight of the hens, feed intake, laying rate, egg weight or egg mass. Enzyme addition at the recommended level decreased significantly the feed to egg mass ratio. No differences were found between treatments regarding the egg quality parameters measured.

3.3.1.3. Conclusions on efficacy for the target species

In one study, supplementation of the diets with the additive increased the AME and AMEn of the diets offered to laying hens. In two other studies, ROVABIO® SPIKY improved the performance of the laying hens. Therefore, the FEEDAP Panel concludes that the additive has the potential to be efficacious in laying hens at the recommended dose. The Panel considers that the efficacy established in laying hens applies also to breeding hens and as the mode of action of xylanase and glucanase can be reasonably assumed to be the same in all avian species, the conclusions on the efficacy for laying hens can be extrapolated to include all minor poultry species for laying.

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 Regulation¹⁴ and good manufacturing practice.

4. Conclusions

The new use of the additive would not change the conclusions drawn previously regarding the safety for consumer, user and environment. The Panel concluded that the additive is safe for the consumer and the environment; the additive is not irritant to the skin or eyes but should be considered a potential skin sensitiser and potentially harmful if inhaled.

The additive is safe and efficacious for all poultry species at the recommended dose (1,100 U xylanase and 760 U glucanase per kg feed).

¹³ Technical dossier/Section IV/Annex IV.1.3.B and Supplementary information May 2016/Annex 3.

¹⁴ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

Documentation provided to EFSA

- 1) ROVABIO® SPIKY for all poultry species. October 2015. Submitted by Adisseo France S.A.S.
- 2) ROVABIO® SPIKY for all poultry species. Supplementary information. May 2016. Submitted by Adisseo France S.A.S.
- 3) Comments from Member States.

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Abbreviations

AME	apparent metabolisable energy
AMEn	nitrogen-corrected AME
ANOVA	analysis of variance
DNS	3,5-dinitrosalicylic acid
EURL	European Union Reference Laboratory
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed