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# Safety and efficacy of a feed additive consisting of the seed husk of *Plantago ovata* Forssk. for use in cats and dogs (C.I.A.M.)

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## 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 the seed husk of *Plantago ovata* Forssk. when used as a sensory additive in feed for cats and dogs. The additive is described as a mixture of mucopolysaccharides and specification is given as swelling index $\geq$ 40, which is considered as the marker parameter. Since the composition of the additive remained uncharacterised, and considering the limitations in the toxicological data set, the FEEDAP Panel was unable to conclude on the safety for the target species. In the absence of data, no conclusions can be drawn on the safety for the user. In the absence of evidence that the additive acts as a flavour in animal feed or has an effect on palatability, the FEEDAP Panel was unable to conclude on the efficacy of the additive.

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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 10(2) of that Regulation specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, within a maximum of seven years after the entry into force of this Regulation.

The European Commission received a request from C.I.A.M. S.r.l.[2] for re-evaluation of the product *Plantago ovata L.*[3] husk (Fleawort absolute), when used as a feed additive for cats and dogs (category: sensory additives; functional group: flavouring compounds).

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 10(2) (re-evaluation of an authorised 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 4 June 2018.

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 and the user, and on the efficacy of the product *P. ovata* husk, when used under the proposed conditions of use (see Section 3.2.3).

## 1.2. Additional information

*Plantago ovata* L. (Fleawort absolute) is currently listed in the European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 (2b natural products – botanically defined). It has not been previously assessed by EFSA as feed additives.

Ispaghula husk (*Plantaginis ovatae seminis tegumentum*) is described in a monograph of the European Pharmacopoeia (PhEur, 2020, 01/2020:1334) as episperm and collapsed adjacent layers removed from the seeds of *P. ovata* Forssk. (*P. ispaghula* Roxb).[4] According to the European Pharmacopoeia, the husk consists of pinkish-beige fragments or flakes up to about 2 mm long and 1 mm wide, some showing a light brown spot corresponding to the location of the embryo before it is removed from the seed.

The extract from the seeds of *P. ovata* are listed in the European list of Cosmetics and Ingredients and Substances as skin conditioning.[5]

The European Medicines Agency (EMA) issued a European Union herbal monograph on *P. ovata* Forssk., seminis tegumentum (EMA, 2013a)[6] and an assessment report on *Plantago ovata* Forssk., seminis tegumentum (EMA, 2013b).

*Semen Plantaginis* (plantago seeds) is described in the WHO monograph as the dried, ripe seed of *Plantago afra* L., *P. indica* L. *P. ovata* Forssk. (synonym: *P. ispaghula* Roxb.) or *P. asiatica* L. (Plantaginaceae) (WHO, 1999).[7]

# 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[8] in support of the re-evaluation of *P. ovata* seed husk as a feed additive for cats and dogs.

[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] C.I.A.M. S.r.l., via Piemonte 4, 63100 Ascoli Piceno (AP), Italy.
[3] Accepted name: *Plantago ovata* Forssk., synonym *Plantago ispaghula* Roxb. ex Fleming.
[4] Technical dossier/Section II/Ref_II_1_03_CoE_2008.
[5] Commission Decision 2006/257/EC of 9 February 2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products, OJ L 97, 5.4.2006, p. 1–528.
[6] Technical dossier/Section II/Ref_II_1_07 and Ref_II_1_02_EMEA_2006.
[7] Technical dossier/Section II/Ref_II_1_07 and Ref_II_1_04_WHO_1999.
[8] FEED dossier reference: FAD-2010-0327.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts', to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the additive's phytochemical markers in animal feed. The Executive Summary of the EURL report can be found in Annex A.[9]

## 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *P. ovata* seed husk is in line with the principles laid down in Regulation (EC) No 429/2008[10] and the relevant guidance documents: Guidance for the preparation of dossiers for sensory additives (EFSA FEEDAP Panel, 2012a), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b) and Guidance on the assessment of additives intended to be used in pets and other non-food-producing animals (EFSA FEEDAP Panel, 2011).

# 3. Assessment

The additive under assessment, *P. ovata* seed husk, is prepared from the seed husk of *P. ovata* Forssk. and is intended for use as a sensory additive (functional group: flavouring compounds) in feed for cats and dogs.

## 3.1. Origin

*Plantago ovata* Forssk. (synonym *Plantago ispaghula* Roxb. ex Fleming) is an annual herb belonging to the family of Plantaginaceae. It is said to be native to the Mediterranean region but is now naturalised in many parts of the world. Common names include blond or Indian plantain and blond psyllium, the term 'psyllium' being often used for the plant, the seeds or the seed husks without distinguishing between different *Plantago* species and/or their parts. The trivial name fleawort or flea-wort may be found associated with some *Plantago* species, but the name is also applied to several other genera of plants, *P. ovata* is one of several species of *Plantago* commercially grown for the production of seeds and/or their husks as a soluble form of fibre with a high water-binding capacity.

The additive is prepared by dehusking the seeds of *P. ovata*. The husks are then ground, sieved and pasteurised by treatment with steam before packaging as a powder.

## 3.2. Characterisation

### 3.2.1. Characterisation of the additive

*P. ovata* seed husk is identified by the Chemical Abstract Service (CAS) number 90082-86-3 and the European Inventory of Existing Commercial chemical Substances (EINECS) number 290-178-8. The additive consists of 85% water-soluble fibre and is relatively resistant to fermentation by colonic bacteria.

The additive is described as a mixture of mucopolysaccharides. The polymer backbone is claimed to be a xylan with 1→3 and 1→4 linkages, with no apparent regularity in their distribution. The monosaccharides in this main chain are substituted on C-2 or C-3 by L-arabinose, D-xylose and α-D-galacturonyl-(1→2)-L-rhamnose (WHO, 1999). However, no analytical data were provided to support the description of the additive.

According to the specification proposed by the applicant, *P. ovata* seed husk has a swelling index (selected as the marker parameter) of at least 40, a content of ash ≤ 4% and loss on drying is specified to be ≤ 12%. Analysis of seven batches of the additive showed compliance with specification.[11] However, certificates of analysis were not provided. The FEEDAP Panel notes that the swelling index is not an acceptable means of describing the composition of the additive. Besides the swelling index, the applicant indicated verbascosides as a phytochemical marker without specifying a range of its mass fraction in the additive. Analytical data were not provided.

[9] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2010-0327-plantago-ovata-husk.pdf

[10] 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.

[11] Technical dossier/Section II/Annex II_1_02_ Analysis batches.

The applicant did not provide the full characterisation of the additive, despite being requested. In the absence of this information, uncertainty remains concerning the composition of the additive.

The applicant provided commercial information sheets of *P. ovata* seed husk,[12] which include statements of compliance for chemical impurities and microbiological contamination. Specifications for chemical impurities include heavy metals (lead ≤ 3.0 mg/kg, cadmium ≤ 1.0 mg/kg and mercury ≤ 0.1 mg/kg) and mycotoxins (aflatoxin B1 ≤ 5.0 μg/kg, aflatoxins B1, B2, G1 and G2 ≤ 10.0 μg/kg) and pesticide residues, which are declared to comply with the maximum limits of Regulation (EU) No 396/2005[13]). Specifications for microbial contamination include aerobic bacteria ≤ 500,000 colony forming unit (CFU)/g, fungi (yeasts/moulds) ≤ 50,000 CFU/g, Gram-negative bacteria ≤ 10,000 CFU/g, *Salmonella* spp. absent in 25 g, *Escherichia coli* absent in 1 g. However, analytical data supported by certificates of analysis were not provided. The FEEDAP Panel notes that the specifications for aerobic bacteria, fungi and Gram negative are very high.

Particle size analysis (by sieving) of the additive showed that 90% of particles is < 300 μm. The fraction of particles < 50 μm ranged from 38% to 57% in three batches of the additive. No data was provided on the dusting potential of the additives.

### 3.2.2. Stability

The typical shelf-life of the additive under assessment is stated to be at least 3 years when stored in closed containers protected from heat, light and humidity.[14] Stability studies were made using swelling index (the marker compound) in three batches of *P. ovata* seed husk over a 3-year storage (temperature not reported).[15]

Stability in feedingstuffs of *P. ovata* seed husk was tested in a cat feed at 25 °C by monitoring the content of verbascosides.[16] After 18-month storage, 52.1% of the initial content of verbascosides was present in the feed. When the stability in cat feed was tested at different temperatures, the verbascosides recovery was 95, 88 and 27% after 63-day storage at 25, 45 and 60°C, respectively. At 80°C, verbascosides was no longer present after 32 days.

### 3.2.3. Conditions of use

*P. ovata* seed husk is intended for use in feedingstuffs, premixtures and complementary feed for cats and dogs up to the maximum use level of 50 mg/kg complete feed.

## 3.3. Safety for the target species and the user

Tolerance studies and/or toxicological studies made with the additive under application were not submitted. In addition, the additive is not sufficiently characterised to allow an assessment based on the individual components.

No specific studies were provided on absorption, distribution, metabolism and excretion with the additive under assessment and with the individual constituents.

The applicant made reference to the EMA herbal monograph on *P. ovata* seminis tegumentum, where the subchronic toxicity of *P. ovata* seed husk is described (EMA, 2013a). 'Ispaghula husk was fed to rats at levels high as 10% of the diet for periods up to 13 weeks (three 28-day studies, one 13-week study). The consumption ranged from 3,876 to 11,809 mg/kg/day (3-16 times of the human dosage calculated for a 60 kg human). Effects seen were lower serum total protein, albumin, globulin, total iron-binding capacity, calcium, potassium, and cholesterol; and higher aspartate transaminase and alanine transaminase activities relative to control. The absence of any increases in urinary protein and any differences in growth or feed efficiency in ispaghula husk fed rats may give evidence that there are no adverse effects on protein metabolism. Because the absorption of ispaghula husk is very limited, histopathological evaluations were limited to the gastrointestinal tract, liver, kidneys and gross lesions without observing any treatment-related effect'.

[12] Technical dossier/Section II/Annex II_1_01_Data_sheet_Plantago_ovata.
[13] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EECText with EEA relevance. OJ L 70, 16.3.2005, p. 1–16.
[14] Technical dossier/Section II/Annex II_4_01_Stability statement of supplier.
[15] Technical dossier/Section II/Annex II_4_02_Stability shelf life.
[16] Technical dossier/Section II/Annex II_4_03_Stability feedingstuff.

In the assessment report on *P. ovata* Forssk., seminis tegumentum (EMA, 2013b), EMA concluded that 'The non-clinical data on toxicology of ispaghula husk preparations are incomplete, but available data indicate no signals of toxicological concern. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been published'.

In the absence of data on the full characterisation of the additive and considering the limitations in the toxicological data set, the FEEDAP Panel cannot conclude on the safety of the additive for cats and dogs.

No specific data were provided by the applicant regarding the safety of the additive for the user and, consequently, no conclusions can be drawn on the potential of the additive to be dermal/eye irritant or skin sensitiser. Allergic reactions to *Plantago* products following inhalation have been reported (WHO, 1999). The additive contains 38–57% of particles of thoracic size (< 50 μm). In the absence of data on their dusting potential it is not possible to estimate exposure of users to dust.

In the absence of adequate data, the FEEDAP Panel cannot conclude on the safety of the additive under assessment for the target animals or the users.

### 3.4. Efficacy

*Plantago ovata* is not listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2010) or by the Flavour and Extract Manufactures Association (FEMA).

In the absence of evidence that the additive acts as a flavour in animal feed or has an effect on palatability, the FEEDAP Panel is unable to conclude on the efficacy of the additive.

## 4. Conclusions

In the absence of data on the full characterisation of the additive and considering the limitations in the toxicological data set, the FEEDAP Panel cannot conclude on the safety of the seed husk of *Pl. ovata* Forssk. at the proposed use levels of up to 50 mg/kg complete feed for cats and dogs.

In the absence of data, no conclusions can be drawn on the safety for the user.

In the absence of evidence that the additive acts as a flavouring in animal feed or has an effect on palatability, the FEEDAP Panel is unable to conclude on the efficacy of the additive.

## 5. Documentation as provided to EFSA/Chronology

| Date | Event |
|---|---|
| 05/11/2010 | Dossier received by EFSA. *Plantago ovata* L. (Fleawort absolute) for cats and dogs. Submitted by C.I.A.M. S.r.l. |
| 25/05/2018 | Reception mandate from the European Commission |
| 04/06/2018 | Application validated by EFSA – Start of the scientific assessment |
| 22/06/2018 | Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterization, safety for the target species, safety for the user, efficacy* |
| 05/09/2018 | Comments received from Member States |
| 11/10/2019 | The applicant informed the European Commission on the impossibility to provide the information requested in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 |
| 29/10/2020 | Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives - Scientific assessment re-started |
| 28/01/2021 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment |

## References

Burdock GA, 2010. Fenaroli's Handbook of Flavor Ingredients, 6th Edition. CRC Press, Taylor & Francis Group, Boca Raton.

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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. https://doi.org/10.2903/j.efsa.2012.2539

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance for the preparation of dossiers for sensory additives. EFSA Journal 2012;10(1):2534, 26 pp. https://doi.org/10.2903/j.efsa.2012.2534

EMA (European Medicines Agency), 2013a. Community herbal monograph on *Plantago ovata* Forssk., seminis tegumentum. EMA/HMPC/199774/2012. Committee on Herbal Medicinal Products (HMPC). Available online: https://www.ema.europa.eu/en/documents/herbal-monograph/final-community-herbal-monograph-plantago-ovata-forssk-seminis-tegumentum_en-0.pdf

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## Abbreviations

| | |
|---|---|
| CAS | Chemical Abstracts Service |
| CFU | colony forming unit |
| EINECS | European Inventory of Existing Commercial chemical Substances |
| EMA | European Medicines Agency |
| EURL | European Union Reference Laboratory |
| HPLC-DAD-MS/MS | high-performance liquid chromatography coupled to diode array detection and triple quadrupole mass spectrometry. |
| TLC | thin-layer chromatography |
| WHO | World Health Organization |

# Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for verbascosides in *Plantago ovata* L. husk: fleawort absolute

In the current application an authorisation is sought under Article 10(2) for the botanically defined *Plantago ovata L. husk: fleawort absolute* under the category/functional group (2 b) "sensory additives"/"flavouring compounds", according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, the *feed additive* is sought to be used for cats and dogs.

The *feed additive* is a powder consisting of a mixture of chemical components naturally present, namely mucopolysaccharides. The Applicant specified *verbascosides* as a phytochemical marker for *Plantago ovata L. husk: fleawort absolute* without specifying a range of its mass fraction in the *feed additive*. In addition, the Applicant specified for the characterisation of the *feed additive* criteria for three parameters as defined by the European Pharmacopoeia Monograph 01/2008:1334, namely a minimum value of 40 for the swelling index, and maximum values of 12% (w/w) for the loss on drying and 4% (w/w) for total ash content.

The *feed additive* is intended to be incorporated directly into *feedingstuffs* or through *premixtures*. The Applicant did not propose a minimum or a maximum level of the *feed additive.* However, a maximum content of 50 mg *feed additive*/kg *feedingstuffs* was suggested by the Applicant.

For the determination of the phytochemical marker (*verbascosides*) in the *feed additive* the Applicant submitted an in-house method based on high performance liquid chromatography coupled to diode array detection and triple quadrupole mass spectrometry (HPLC-DAD-MS/MS). However, neither validation nor verification data of the method were submitted by the Applicant. Furthermore, the Applicant did not specify the target content of *verbascosides* as a criterion in the *feed additive*.

Therefore, based on the available information, the EURL is not able to recommend for official control the HPLC-DAD-MS/MS or any other method for the determination of *verbascosides* in the *feed additive*.

For further characterisation of the *feed additive* the Applicant proposed the methods for the determination of the swelling index, loss on drying and total ash content, and presented acceptable data from the analysis of different batches of the *feed additive*. For the identification of the *feed additive* the Applicant did not submit proofs of the applicability of a more specific method based on thin-layer chromatography (TLC) as described in the mentioned European Pharmacopoeia Monograph.

Based on the available information, the EURL considers that the methods for the determination of the swelling index, loss on drying and total ash content are fit-for purpose and might be recommended for official control for the characterisation of the *feed additive*, but only if combined with a more specific method, namely thin-layer chromatography (TLC), which was not demonstrated as fit-for-purpose.

As the unambiguous determination of the *feed additive* added to *premixtures* and *feedingstuffs* is not achievable experimentally, the EURL cannot evaluate or recommend any method for official control for the determination of *Plantago ovata L. husk: fleawort absolute* in these matrices.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.