

ADOPTED: 28 January 2021

doi: 10.2903/j.efsa.2021.6446

Safety and efficacy of feed additives consisting of dried extracts from *Echinacea angustifolia* DC. or *Echinacea purpurea* (L.) Moench 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 dried extracts prepared from the dried roots of *Echinacea angustifolia* DC. or the dried aerial parts of *Echinacea purpurea* (L.) Moench, when used as sensory feed additives for cats and dogs. *E. angustifolia* extract is specified to contain at least 4% echinacosides and *E. purpurea* extract at least 4% total phenols. Since about 75% of the composition of the extracts remained uncharacterised, 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 potential of the extracts to be dermal/eye irritants or skin sensitisers. In the absence of evidence that the extracts act as flavours in animal feed or have an effect on palatability, the FEEDAP Panel was unable to conclude on the efficacy of the additives.

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Keywords: sensory additives, *Echinacea angustifolia* DC., *Echinacea purpurea* (L.) Moench, echinacoside, polyphenols, safety, efficacy

Requestor: European Commission

Question number: EFSA-Q-2018-00319

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Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

Acknowledgements: The Panel wishes to acknowledge the contribution of Jaume Galobart and Gloria López-Gálvez to this opinion.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Durjava MF, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Brantom P, Chesson A, Westendorf J, Manini P, Pizzo F and Dusemund B, 2021. Scientific Opinion on the safety and efficacy of feed additives consisting of dried extracts from *Echinacea angustifolia* DC. or *Echinacea purpurea* (L.) Moench for use in cats and dogs (C.I.A.M.). EFSA Journal 2021;19(3):6446, 9 pp. <https://doi.org/10.2903/j.efsa.2021.6446>

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.



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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 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 *Echinacea angustifolia* DC. (Blacksamson echinacea extract) and *Echinacea purpurea* (L.) Moench (Echinacea extract), 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 22 May 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 products *E. angustifolia* DC. (Blacksamson echinacea extract) and *E. purpurea* (L.) Moench (Echinacea extract), when used under the proposed conditions of use (see Section 3.2.3).

1.2. Additional information

Echinacea purpurea (L.) Moench (Echinacea extract) and *Echinacea angustifolia* DC. (Blacksamson echinacea extract) are currently listed in the European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 (2b natural products – botanically defined). They have not been previously assessed by EFSA as feed additives.

Echinacea and *E. purpurea* are listed as active medicinal ingredients for all food-producing species without a maximum residue limit (MRL).³

Extracts from the roots of *E. angustifolia* and the whole plant of *E. purpurea* are listed in the European list of Cosmetics and Ingredients and Substances.⁴

For human traditional medicinal uses the European Medicines Agency (EMA) issued assessment reports and herbal monographs on *E. angustifolia* DC., radix, *E. purpurea* (L.) Moench, herba recens and *E. purpurea* (L.) Moench, radix, respectively (EMA, 2012a,b, 2015a,b, 2017a,b).

Narrow-leaved coneflower root (*E. angustifoliae* radix) is described as dried, whole or cut underground parts of *E. angustifolia* (D.C.) in a monograph of the European Pharmacopoeia (PhEur, 2020, 01/2020:1821).⁵ Purple coneflower root (*E. purpureae* radix) is described in a monograph of the European Pharmacopoeia (European Pharmacopoeia, 10th Edition, 2020, 01/2020:1824) as dried, whole or cut underground parts of *E. purpurea* (L.) Moench.⁶ In a separate monograph (European Pharmacopoeia, 10th Edition, 2020, 01/2020:1823),⁷ purple coneflower herb (*E. purpurea* herba) is described as dried, whole or cut flowering aerial parts of *E. purpurea* (L.) Moench.

Radix Echinaceae (*E. angustifolia* DC) and Herb Echinaceae Purpureae (*E. purpurea* (L.) Moench) are described in two separate WHO monographs (WHO, 1999a,b).⁸

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 Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15/1, 20.1.2010, p. 15.

⁴ 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.

⁵ Technical dossier/Section II/Ref_II_1_06.

⁶ Technical dossier/Section II/Ref_II_1_04.

⁷ Technical dossier/Section II/Ref_II_1_05.

⁸ Technical dossier/Section II/Ref_II_1_07 and Ref_II_1_08.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁹ in support of the re-evaluation of dried extracts from *E. angustifolia* DC. and *E. purpurea* (L.) Moench as feed additives.

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.¹⁰

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of dried extracts from *E. angustifolia* DC. and *E. purpurea* (L.) Moench, is in line with the principles laid down in Regulation (EC) No 429/2008¹¹ 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 additives under assessment are dried extracts from *E. angustifolia* DC. and *E. purpurea* (L.) Moench, intended for use as sensory additives (functional group: flavouring compounds) in feed for cats and dogs.

3.1. Origin and extraction

E. angustifolia and *E. purpurea* are perennial herbs, belong to the family of Asterales and are native to North America. Both are now widely cultivated as ornamental species in temperate parts of the world. Many common names, such as purple coneflower or Blacksamson, are indiscriminately applied to both. There is a long history of traditional medicinal use of both plant species dating back to native Americans.

The extract from *E. purpurea* is obtained from the dried and ground aerial parts of the plant by extraction with ethanol at 60°C. After extraction the insoluble plant biomass is removed by centrifugation and the ethanol extract concentrated by evaporation. Maltodextrin is added and the concentrated extract spray dried. Further maltodextrin may be added to standardise the dried product.

The *E. angustifolia* extract is prepared only from the dried and ground roots by extraction with methanol at 30°C. Following separation from the biomass, the methanol extract is treated in the same manner as the *E. purpurea* extract.

3.2. Characterisation

3.2.1. Characterisation of the extracts

E. angustifolia dry extract is identified by the Chemical Abstract Service (CAS) number 84696-11-7 and the European Inventory of Existing Commercial chemical Substances (EINECS) number 283-631-6, *E. purpurea* dry extract by the CAS number 900028-20-9 and EINECS number 289-808-4. The additives are described as a brown fine powder, with a characteristic odour. Both have a density of 450–600 kg/m³. The additives are partially soluble in water and organic solvents (good blending in alcohol).

According to the specification proposed by the applicant, *E. angustifolia* dry extract contains at least 4% echinacoside (selected as the marker compound) and *E. purpurea* dry extract at least 4%

⁹ FEED dossier reference: FAD-2010-0332.

¹⁰ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2010-0332-echinacea-extract.pdf>

¹¹ 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.

total phenols (selected as the marker compounds). For both additives, loss on drying is specified to be $\leq 5\%$, and ash $\leq 15\%$. The applicant provided data for five batches of *E. angustifolia* extract, which showed an average content of echinacoside of 3.7% (range 2.8–4.9%).¹² Three out of the five batches did not comply with the minimum specification proposed by the applicant. The content of total polyphenols in eight batches of *E. purpurea* extract was on average 4.7% (range 4.1–10.5%).¹³ For both extracts certificates of analysis were not provided.

The applicant did not provide the full characterisation of the additives, despite being requested. In the absence of this information, uncertainty remains concerning 75% of the composition of the extracts.

The applicant provided commercial information sheets of *E. angustifolia*¹⁴ and *E. purpurea*,¹⁵ 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), mycotoxins (aflatoxin B1 ≤ 5.0 µg/kg, aflatoxins B1, B2, G1 and G2 ≤ 10.0 µg/kg), residual solvents (ethanol $\leq 0.5\%$ in *E. angustifolia* extract, methanol $\leq 0.3\%$ in *E. purpurea* extract, both below the thresholds proposed by International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (EMA, 2010)) and pesticide residues (which are declared to comply with the maximum limits of Regulation (EU) No 396/2005¹⁶). For both extracts, specifications for microbial contamination include aerobic bacteria $\leq 50,000$ colony forming unit (CFU)/g, fungi (yeast/moulds) ≤ 500 CFU/g, Gram negative bacteria ≤ 100 CFU/g, *Salmonella* spp. absent in 25 g, *E. coli* absent in 1 g. However, analytical data supported by certificates of analysis were not provided. The FEEDAP Panel notes that the specification for aerobic bacteria is very high.

Particle size analysis (by sieving) of both formulated additives showed that 90% of particles is < 300 µm. The fraction of particles < 50 µm was 32.9% in one batch of *E. angustifolia* dry extract and ranged from 35.4 to 82.5% in three batches of *E. purpurea* dry extract. No data were provided on the dusting potential of the additives.

3.2.2. Stability

The applicant stated that the typical shelf-life of Echinacea extracts is at least 3 years when stored in closed containers protected from heat, light and humidity.¹⁷ Stability studies done by the applicant showed that the content of echinacoside (the marker compound) was 81% in three batches of *E. angustifolia* extract after 3-year storage (temperature not reported). For *E. purpurea* the content of total polyphenols (the marker compounds) determined in three batches was 115% after 3-year storage (temperature not reported).¹⁸

Stability in feedingstuffs of *E. angustifolia* dry extract was tested in a cat feed at 25°C.¹⁹ After 18-month storage, 77.3% of the initial content of echinacoside was present in the feed. When the stability in cat feed was tested at different temperatures, the echinacoside content was 97, 94, 81 and 69% after 53-day storage at 25, 45, 60 and 80°C, respectively.

3.2.3. Conditions of use

Echinaceae extracts are intended for use in feedingstuffs, premixtures and complementary feed for cats and dogs, up to the maximum use level of 40 mg/kg complete feed.

3.3. Safety for the target species and the user

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

¹² Technical dossier/Section II/Annex II_1_03_Batch to batch *E. angustifolia*.

¹³ Technical dossier/Section II/Annex II_1_03_Batch to batch *E. purpurea*.

¹⁴ Technical dossier/Section II/ Annex II_1_01_Analysis *E. angustifolia*.

¹⁵ Technical dossier/Section II/ Annex II_1_02_Analysis *E. purpurea*.

¹⁶ 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/EEC. OJ L 70, 16.3.2005, p. 1–16.

¹⁷ Technical dossier/Section II/ Annex II_4_01_Stability statement of supplier.

¹⁸ Technical dossier/Section II/ Annex II_4_02_Stability shelf life.

¹⁹ Technical dossier/Section II/ Annex II_4_03_Stability feedingstuff.

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

In the absence of specific safety studies of the additives and considering that there is uncertainty about the composition of 75% of the additives, the FEEDAP Panel cannot conclude on the safety of the additives for cats and dogs.

No specific data were provided by the applicant regarding the safety of the additives for the user and, consequently, no conclusions can be drawn on the additives' potential to be dermal/eye irritant or skin sensitisers. The additives contain 30–80% 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 additives under assessment for the target animals or the users.

3.4. Efficacy

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

In the absence of evidence that the extracts act as a flavour in animal feed or have an effect on palatability, the FEEDAP Panel is unable to conclude on the efficacy of the additives.

4. Conclusions

Since no specific safety studies of the additives were provided and considering that 75% of the additives remain uncharacterised, the FEEDAP Panel cannot conclude on the safety of the dried extracts derived from *E. angustifolia* (D.C.) and *E. purpurea* (L.) Moench at the proposed use levels of up to 40 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 extracts act as a flavour in animal feed or have an effect on palatability, the FEEDAP Panel is unable to conclude on the efficacy of the additives.

5. Documentation as provided to EFSA / Chronology

Date	Event
05/11/2010	Dossier received by EFSA. <i>Echinachea angustifolia</i> DC. extract (Blacksamson echinacea extract) and <i>Echinachea purpurea</i> (L.) Moench extract (Echinacea extract) for cats and dogs. Submitted by C.I.A.M. S.r.l.
24/04/2018	Reception mandate from the European Commission
25/05/2018	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. <i>Issues: characterization, safety for the target species, safety for the user, efficacy</i>
23/08/2018	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

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Abbreviations

CAS	Chemical Abstracts Service
CFU	colony forming unit
DM	dry matter
EINECS	European Inventory of Existing Commercial chemical Substances
EMA	European Medicines Agency
EURL	European Union Reference Laboratory
FEMA	Flavour and Extract Manufacturers Association
HPLC	high-performance liquid chromatography
UV	ultraviolet
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 echinacoside in *Echinacea angustifolia* DC. extract and total polyphenols in *Echinacea purpurea* (L.) Moench extract

In the current application an authorisation is sought under Article 10(2) for the botanically defined *feed additives*, namely *Echinacea angustifolia* DC. extract and *Echinacea purpurea* (L.) Moench. extract 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 additives* are sought to be used for cats and dogs.

According to the Applicant, the phytochemical markers for the characterisation of the *feed additives* are *echinacoside* in *Echinacea angustifolia* DC. extract and *total polyphenols* in *Echinacea purpurea* (L.) Moench. extract. The minimum content of each marker in the *feed additives* is 4.0% (w/w). In addition, the Applicant specified *cichoric acid* as a phytochemical marker for *Echinacea purpurea* (L.) Moench. extract without specifying a range of its mass fraction in the *feed additive*.

For the quantification of *echinacoside* in the *feed additive* (*Echinacea angustifolia* DC. extract) the Applicant proposed a method based on high performance liquid chromatography (HPLC) with UV detection at 330 nm described in the European Pharmacopoeia monograph (corrected 6.0, 01/2008:1821).

Based on the acceptable performance data of the method, the EURL recommends the HPLC-UV method described in the above mentioned European Pharmacopoeia monograph for the quantification of *echinacoside* in the *feed additive* (*Echinacea angustifolia* DC. extract).

For the quantification of *total polyphenols* in the *feed additive* (*Echinacea purpurea* (L.) Moench. extract) the Applicant submitted an in-house method based on spectrophotometry at 715 nm after derivatisation with Folin’s-Denis reagent. However, neither validation nor verification data of the method were submitted by the Applicant.

Therefore, based on the available information the EURL is not able to recommend for official control the above mentioned in-house method based on spectrophotometry or any other method for the quantification of *total polyphenols* in the *feed additive* (*Echinacea purpurea* (L.) Moench. extract).

For further identification/characterisation of *Echinacea purpurea* (L.) Moench. extract the EURL recommends the HPLC-UV based method as proposed by the Applicant and described in the European Pharmacopoeia monographs (corrected 6.0, 01/2008:1823 and 01/2008:1824) for the qualitative analysis of *cichoric acid* in the *feed additive* (*Echinacea purpurea* (L.) Moench. extract).

As the unambiguous determination of the *feed additives* added to *premixtures* and *feedingstuffs* is not achievable experimentally, the EURL cannot evaluate or recommend any method for official control for the determination of *Echinacea angustifolia* DC. extract and *Echinacea purpurea* (L.) Moench. extract 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.