SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 28 January 2021

doi: 10.2903/j.efsa.2021.6444

Safety and efficacy of a feed additive consisting of a dried extract from *Garcinia gummi-gutta* (L.) Roxb. 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 extract from *Garcinia gummi-gutta* (L.) Roxb. (Garcinia extract) when used as a sensory additive in feed for cats and dogs. Garcinia extract is specified to contain at least 60% hydroxycitric acid. Since about 25% of the composition of the extract remained uncharacterised and in the absence of complete toxicological data, the FEEDAP Panel was unable to conclude on the safety for cats and dogs. In the absence of adequate data, no conclusions can be on the safety for the user. In the absence of evidence that the extract 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.

Keywords: sensory additives, *Garcinia gummi-gutta* (L.) Roxb., Garcinia extract, hydroxycitric acid, safety, efficacy

Requestor: European Commission

Question number: EFSA-Q-2018-00440

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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.

Acknowledgments: The Panel wishes to acknowledge the contribution of Jaume Galobart, Matteo Innocenti and Jordi Tárres-Call 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 a feed additive consisting of a dried extract from *Garcinia gummi-gutta* (L.) Roxb. for use in cats and dogs (C.I.A.M.). EFSA Journal 2021;19(3):6444, 8 pp. https://doi.org/10.2903/j.efsa.2021.6444

ISSN: 1831-4732

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 1831/2003[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 *Garcinia cambogia* Desrouss.[3] (Garcinia 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 4 April 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 *G. cambogia* (Garcinia extract), when used under the proposed conditions of use (see Section 3.2.3).

1.2. Additional information

Garcinia cambogia Desrouss. (Garcinia extract) 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 a feed additive.

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[4] in support of the authorisation request for the use of Garcinia dry extract as a feed additive for cats and dogs.

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 phytochemical markers in animal feed. The Executive Summary of the EURL report can be found in Annex A.[5]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Garcinia dry extract is in line with the principles laid down in Regulation (EC) No 429/2008[6] 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), Guidance on the assessment of additives intended to be used in pets and other non-food-producing animals (EFSA FEEDAP Panel, 2011).

[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: *Garcinia gummi-gutta* (L.) Roxb., synonym: *Garcinia cambogia* (Gaertn.) Desr.
[4] FEED dossier reference: FAD-2010-0311.
[5] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep_fad-2010-0311_garcinia_extract.pdf
[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.

3. Assessment

The additive under assessment is a dried extract from the fruit peel of *Garcinia gummi-gutta* (L.) Robx. (Garcinia dry extract) and is intended for use as sensory additives (functional group: flavouring compounds) in feed for cats and dogs.

3.1. Origin and extraction

Garcinia gummi-gutta (L.) Robx. (synonym: *Garcinia cambogia* (Gaertn.) Desr.) is a small tree species belonging to the Clusiaceae family. It is native to Indonesia but is commonly grown in India and elsewhere South East Asia either for its small pumpkin-like fruit used in cooking or for its resin which is used as a dye. Common names include bindleberry or Malabar tamarind or, in reference to the dye, camboge.

Garcinia extract is obtained from the chopped and crushed peel of the fruit of *G. gummi-gutta* by extraction with water at ambient temperature. Following the extraction phase, the insoluble biomass is separated, and the aqueous extract is partially concentrated by evaporation and then lime is added. The resultant precipitate is separated by filtration, maltodextrin is added as a carrier, and the extract is dried.

3.2. Characterisation

3.2.1. Characterisation of the extract

Garcinia dry extract is identified by the Chemical Abstract Service (CAS) number 90045-23-1 and the European Inventory of Existing Commercial chemical Substances (EINECS) number 289-882-8. The additive is described as a whitish fine powder, with a characteristic odour. It has a density of 400–700 kg/m^3 and is partially soluble in water and organic solvents (good blending in alcohol). The pH of a 10% solution ranges between 4 and 8.

By specification, Garcinia dry extract contains at least 60% hydroxycitric acid (selected as the marker compound). Loss on drying is specified to be ≤ 5%. Analysis of five batches of Garcinia extract showed an average content of hydroxycitric acid of 68.9% (range 62.8–78.3%) and loss on drying 4.2% (range 1.5–7.9%).[7] However, certificates of analysis were not provided.

The applicant did not provide the full characterisation of the additive, despite being requested. In the absence of this information, uncertainty remains concerning 25% of the composition of the extract.

The applicant provided a commercial information sheet of Garcinia dry extract,[8] which includes 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) and pesticide residues, which are declared to comply with the maximum limits of Regulation (EU) No 396/2005. Specifications for microbial contamination include aerobic bacteria ≤ 50,000 colony forming unit (CFU)/g, fungi (yeasts/moulds) ≤ 500 CFU/g, Gram negative bacteria ≤ 100 CFU/g, *Salmonella* spp. absent in 25 g, *E. coli* absent in 1 g. However, certificates of analysis were not provided. The FEEDAP Panel notes that the specification for aerobic bacteria is very high.

Particle size analysis (by sieving) showed that 90% of particles is < 300 μm. The fraction of particles < 50 μm ranged from 50% to 69% in three batches of Garcinia dry extract.[9] No data was provided on the dusting potential of the additive.

3.2.2. Stability

The typical shelf-life of Garcinia dry extract is stated to be at least 3 years when stored in closed containers protected from heat, light and humidity.[10] Stability studies showed that the loss of hydroxycitric acid (the marker compound) was 1–6% in three batches of Garcinia dry extract after 3-year storage (temperature not reported).[11]

[7] Technical dossier/Section II/Annex_II.1.02_Analysis batches.
[8] Technical dossier/Section II/Annex II_1_01_Data sheet Garcinia extract.
[9] Technical dossier/Section II.
[10] Technical dossier/Section II/Annex II_4_01_Stability statement of supplier.
[11] Technical dossier/Section II/Annex II_4_02_Stability shelf life.

Stability in feedingstuffs of Garcinia dry extract was tested in a cat feed at 25 °C.[12] After 7-month storage, 50% of the initial content of hydroxycitric acid was present in the feed. When the stability in cat feed was tested at different temperatures, the hydroxycitric acid content was 93, 92, 88 and 67% after 26-day storage at 25, 45, 60 and 80°C, respectively.

3.2.3. Conditions of use

Garcinia dry extract is intended for use in feedingstuffs, premixtures and complementary feed for cats and dogs up to the maximum use level of 200 mg/kg complete feed.

3.3. Safety for the target species and the user

No specific studies on absorption, distribution, metabolism and excretion with the extract under assessment in the target species (cats and dogs) were provided.

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

The applicant provided an overview of the available toxicological studies prepared for the National Cancer Institute (NCI) to include *Garcinia cambogia* extract in the testing of the National Toxicology Program (NTP).[13] Genotoxicity studies (Ames test and micronucleus in mice and rats) have been completed but only the results of the Ames test (negative under all conditions tested) have been published. Short-term studies in rat and mice are under review or ongoing.[14]

In the absence of complete toxicological data and considering that there is uncertainty about the composition of 25% of the additive, 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.

In the summary information provided by the applicant,[15] some findings with a *G. gummi-gutta* extract (standardised to contain 60% hydroxycitric acid) gave no indications of skin irritation but indicate the possibility of eye irritation (Ohia et al., 2002). The additive contains 50–70% of particles of thoracic size (< 50 μm). In the absence of data on their dusting potential, it is not possible to estimate user's exposure 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 and the users.

3.4. Efficacy

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

In the absence of evidence that the extract 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

Since the 25% of the additive remains uncharacterised and in the absence of complete toxicological data, the FEEDAP Panel cannot conclude on the safety of the extract derived from the fruit peel of *Garcinia gummi-gutta* (L.) Robx. at the proposed use levels of up to 200 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 extract 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.

[12] Technical dossier/Section II/Annex II_4_03_Stability feedingstuff.
[13] Technical dossier/Section III/Ref_III_01_TR_2004.
[14] https://ntp.niehs.nih.gov/whatwestudy/testpgm/status/ts-m050016.html?utm_source=direct&utm_medium=prod&utm_campaign=ntpgolinks&utm_term=ts-m050016
[15] Technical dossier/Section III/Ref_III_1_01_TRI 2004.pdf.

5. Documentation as provided to EFSA/Chronology

Date	Event
05/11/2010	Dossier received by EFSA. *Garcinia cambogia* Desrouss. (Garcinia extract) for cats and dogs. Submitted by C.I.A.M. S.r.l.
24/05/2018	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
26/10/2020	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.

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Guidance on the assessment of additives intended to be used in pets and other non food-producing animals. EFSA Journal 2011;9(2):2012, 3 pp. https://doi.org/10.2903/j.efsa.2011.2012

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

Ohia SE, Opere CA, LeDay AM, Bagchi M, Bagchi D and Stohs SJ, 2002. Safety and mechanism of appetite suppression by a novel hydroxycitric acid extract (HCA-SX). Molecular Cellular Biochemistry, 238, 89–103.

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 Manufactures Association
MRL	maximum residue limit
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 hydroxycitric acid *in Garcinia cambogia* Desrouss. (Garcinia extract)

In the current application authorisation is sought under Article 10(2) (authorisation of an existing product) for *Garcinia cambogia Desrouss. (Garcinia 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, authorisation is sought for the use of the *feed additive* for dogs and cats.

Garcinia cambogia Desrouss. can be used in *feedingstuffs*, *premixtures* and in complementary feedingstuffs for pets at a recommend maximum level of 200 mg/kg feedingstuffs. According to the Applicant, the phytochemical marker proposed for the characterisation of the *Garcinia extract* is *hydroxycitric acid*. *Garcinia extract* is a natural product and thus the marker component content may vary depending on its geographical origin and/or from harvest to harvest.

For the quantification of *hydroxycitric acid* in the *Garcinia extract* the Applicant submitted an internal method based on reversed phase high performance liquid chromatography (HPLC) coupled to ultraviolet (UV) detection. However, no results from verification experiments have been presented. Consequently, the EURL cannot recommend for official control any analytical method for the quantification of *hydroxycitric acid* in the *Garcinia extract*.

As the unambiguous determination of the *feed additive* added to *premixtures* and *feedingstuffs* is not achievable experimentally the EURL cannot evaluate nor recommend any method for official control for the determination of *hydroxycitric acid* 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.