EUROPEAN COMMISSION
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Directorate F - Health, Consumers & Reference Materials (Geel)
European Union Reference Laboratory for Feed Additives

JRC F.5/CvH/MGH/AS/Ares

Evaluation Report on the Analytical Methods submitted in connection with the Application for Authorisation of a Feed Additive according to Regulation (EC) No 1831/2003

Garcinia cambogia Desrouss. (Garcinia extract)

(FAD-2010-0311; CRL/100288)

European Union Reference Laboratory
Feed Additives

Evaluation Report on the Analytical Methods submitted in connection with the Application for Authorisation of a Feed Additive according to Regulation (EC) No 1831/2003

Dossier related to:	**FAD-2010-0311 - CRL/100288**
Name of Feed Additive:	***Garcinia cambogia Desrouss. (Garcinia extract)***
Active Agent (s):	**hydroxycitric acid**
Rapporteur Laboratory:	**European Union Reference Laboratory for Feed Additives (EURL-FA)** **JRC Geel, Belgium**
Report prepared by:	**María José González de la Huebra**
Report checked by: Date:	**Stefano Bellorini** **23/10/2020**
Report approved by: Date:	**Christoph von Holst** **23/10/2020**

EXECUTIVE SUMMARY

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 *feedingstuff*s, *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 *premixture*s 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.

KEYWORDS

Garcinia cambogia Desrouss. (Garcinia extract), hydroxycitric acid, sensory additives, flavouring compounds, dogs and cats

1. BACKGROUND

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 [1]. Specifically, authorisation is sought for the use of the *feed additive* for dogs and cats [1,2].

The Applicant described the *feed additive (Garcinia extract)* as a whitish fine powder with characteristic odour obtained from the peel of the fruit *Garcinia cambogia Desrouss.* [2,3]. According to the Applicant, the phytochemical marker proposed for the characterisation of the *Garcinia extract* is *hydroxycitric acid* [4]. *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.

Garcinia extract can be used in *feedingstuff*s, *premixtures* and in complementary feedingstuffs for pets at a recommend maximum level of 200 mg/kg *feedingstuffs* [4].

2. TERMS OF REFERENCE

In accordance with Article 5 of Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761, on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and the tasks of the European Union Reference Laboratory concerning applications for authorisations of feed additives, the EURL is requested to submit a full evaluation report to the European Food Safety Authority for each application or group of applications. For this particular dossier, the methods of analysis submitted in connection with *Garcinia cambogia Desrouss*. *(Garcinia extract)* and their suitability to be used for official controls in the frame of the authorisation were evaluated.

3. EVALUATION

Description of the analytical methods for the determination of the active substance in the feed additive, premixtures, feedingstuffs and when appropriate water (section 2.6.1 of the dossier - Annex II of Commission Regulation (EC) No 429/2008)

For the quantification of *hydroxycitric acid* in the *Garcinia extract* the Applicant submitted an in house method based on reversed phase high performance liquid chromatography (HPLC) coupled to ultraviolet (UV) detection [5].

The *Garcinia extract* is dissolved in acidic water (adjusted at pH 2.3 with phosphoric acid), stirred and further diluted. The solution is then filtered through a disposable syringe filter and analysed by reversed phase HPLC. *Hydroxycitric acid* is detected by UV at 210 nm and quantified using an external *hydroxycitric acid* calibration curve [5].

Furthermore, the Applicant applied this method to five different batches of the *feed additive* (*Garcinia extract)* leading to a *hydroxycitric acid* content ranging from 62.8 to 78.3 % [6].

The Applicant did not provide a validation or verification study for the method proposed for the quantification of the phytochemical marker *(hydroxycitric acid)* in the *feed additive* (*Garcinia extract).*

Consequently, the EURL cannot recommend for official control any analytical method for the quantification of *hydroxycitric acid* in the *Garcinia extract.*

Additionally, as the unambiguous determination of the *hydroxycitric acid* added to *premixtures* and *feedingstuffs* is not achievable experimentally the EURL cannot evaluate or recommend any method for official control for the determination of *hydroxycitric acid* in those matrices.

Methods of analysis for the determination of the residues of the additive in food (section 2.6.2 of the dossier - Annex II of Commission Regulation (EC) No 429/2008)

An evaluation of corresponding methods of analysis is not relevant for the present application.

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.

4. CONCLUSIONS AND RECOMMENDATIONS

In the frame of this authorisation the EURL cannot recommend for official control any analytical method for the quantification of *hydroxycitric acid* (phytochemical marker) in the *Garcinia extract.*

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Garcinia cambogia Desrouss*. *(Garcinia extract)* have been sent to the European Union Reference Laboratory for Feed Additives. The dossier has been made available to the EURL by EFSA.

6. REFERENCES

[1] *Application, Ref. SANTE/E5: FORW. APPL. 1831-0018-2018 & Annex I Sub. No. 1288800387630-1388

[2] *Application, Proposal for Register Entry - Annex A

[3] *Technical dossier, Section II.1.2 Proposal for classification

[4] *Technical dossier, Section II.2 Characterisation of the active substance(s)/agent(s) & II.1.5 Conditions of use"

[5] *Technical dossier, Annex II_6-01

[6] *Technical dossier, Section II.1.3 Qualitative and quantitative composition

*Refers to Dossier no: FAD-2010-0311

7. RAPPORTEUR LABORATORY & NATIONAL REFERENCE LABORATORIES

The Rapporteur Laboratory for this evaluation is the European Union Reference Laboratory for Feed Additives, JRC, Geel, Belgium. This report is in accordance with the opinion of the consortium of National Reference Laboratories as referred to in Article 6(2) of Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761.

8. ACKNOWLEDGEMENTS

The following National Reference Laboratories contributed to this report:

- Państwowy Instytut Weterynaryjny, Pulawy (PL)
- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Univerza v Ljubljani. Veterinarska fakulteta. Nacionalni veterinarski inštitut. Enota za patologijo prehrane in higieno okolja, Ljubljana (SI)
- Wageningen Food Safety Research[1] (WFSR) (NL)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Laboratoire de Rennes (SCL L35), Service Commun des Laboratoires DGCCRF et DGDDI, Rennes (FR)
- Laboratori Agroalimentari, Departament d'Agricultura, Ramaderia, Pesca, Alimentació i Medi Natural**.** Generalitat de Catalunya, Cabrils (ES)

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