



**EUROPEAN COMMISSION**  
DIRECTORATE GENERAL  
JOINT RESEARCH CENTRE  
Directorate F – Health, Consumers and Reference Materials  
**European Union Reference Laboratory for Feed Additives**

JRC F.5/CvH/SB/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**

**Arctium lappa extract (Great Burdock extract CoE 57)**  
*(FAD-2010-0301; CRL/100328)*





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in connection with the Application for Authorisation of a  
Feed Additive according to Regulation (EC) No 1831/2003**

Dossier related to: **FAD-2010-0301 - CRL/100328**

Name of Feed Additive: ***Arctium lappa extract (Great Burdock extract CoE 57)***

Phytochemical marker **Inulin**

Rapporteur Laboratory: **European Union Reference Laboratory for  
Feed Additives (EURL-FA)  
JRC Geel, Belgium**

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Date: **04/10/2018**

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Date: **04/10/2018**

## EXECUTIVE SUMMARY

In the current application authorisation is sought under Article 10(2) for the botanically defined *Arctium lappa extract (Great Burdock extract CoE 57)* 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.

According to the Applicant, the phytochemical marker of the *feed additive* is *inulin*; at least 2 % of *inulin* is included in the product.

The *feed additive* is intended to be incorporated directly into *feedingstuffs* or through *premixtures*. The Applicant did not propose a minimum or maximum level of the *feed additive*; however, a maximum content of 40 mg *feed additive*/kg *feedingstuffs* was suggested.

For the determination of the phytochemical marker *inulin* in the *feed additive* the Applicant submitted the ring trial validated AOAC Official Method 997.08 which has the scope to determine added fructans (*inulin* and fructo-oligosaccharides – FOS) in processed foods. The analytical method is based on Ion Exchange Chromatography (IEC) coupled with Pulsed Amperometric Detection (PAD). The Applicant, in the frame of the dossier, presented tests in which the AOAC method for the determination of *inulin* was applied directly to the *feed additive*. Based on the results presented for three different lots of the same product, the EURL calculated a relative standard deviation for repeatability (RSD<sub>r</sub>) of 7.5 %.

Based on the available performance profile, the EURL recommends for official control the ring trial validated AOAC method based on IEC-PAD for the determination of the selected phytochemical marker in the *feed additive*.

The Applicant did not provide experimental data or analytical method for the determination of *Arctium lappa extract* in *premixtures* and *feedingstuffs* as the unambiguous determination of the *feed additive* added to the matrices is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the determination of *Arctium lappa extract* in *premixtures* and *feedingstuffs*.

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

*Arctium lappa extract (Great Burdock extract CoE 57)*, *inulin*, sensory additives, cats and dogs

## 1. BACKGROUND

In the current application authorisation is sought under Article 10(2) (re-evaluation of additives already authorised under the provisions of the Council Directive 70/524/EEC) for the botanically defined *Arctium lappa extract (Great Burdock extract CoE 57)* 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 [1-3]. Specifically, the *feed additive* is sought to be used for cats and dogs [2,3].

The *feed additive* is a brown fine powder containing a mixture of chemical components naturally present such as inulin mucilage, pectin and sugars [4,5]. According to the Applicant, the phytochemical marker of the *feed additive* is *inulin* [3,4]; at least 2 % of *inulin* is included in the product [4].

The *feed additive* is intended to be incorporated directly into *feedingstuffs* or through *premixtures*. The Applicant did not propose a minimum or maximum level of the *feed additive*; however, a maximum content of 40 mg *feed additive*/kg *feedingstuffs* was suggested [6].

## 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 *Arctium lappa extract (Great Burdock extract CoE 57)* 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 determination of the phytochemical marker *inulin* in the *feed additive* the Applicant submitted the ring trial validated AOAC Official Method 997.08 which has the scope to determine added fructans (*inulin* and fructo-oligosaccharides – FOS) in processed foods [7,8].

The analytical method is based on Ion Exchange Chromatography (IEC) coupled with Pulsed Amperometric Detection (PAD).

The fructans are extracted from the sample with boiling water. Part of the extract is enzymatically hydrolysed by using lyophilised amyloglucosidase for removal of starch and maltodextrins. An aliquot of the above mentioned hydrolysate is further hydrolysed enzymatically with inulinase and the released sugars are determined.

Aliquots from the above mentioned extract and from the two hydrolysates are analysed via three IEC-PAD measurements. The content of fructans (*inulin* and FOS) is calculated by subtracting the glucose, sucrose and fructose contents measured in the extract and in the first hydrolysate from the total fructose and glucose content as measured in the second hydrolysate. Furthermore the Applicant applied the above mentioned AOAC method to different batches of *Arctium lappa extract* for the determination of *inulin* [4]. Based on the results presented for three different lots of the same product, the EURL calculated a relative standard deviation for repeatability (RSD<sub>r</sub>) of 7.5 % [9].

Based on the available performance profile, the EURL recommends for official control the ring trial validated AOAC method based on IEC-PAD for the determination of the proposed phytochemical marker in the *feed additive*.

The Applicant did not provide experimental data or analytical method for the determination of *Arctium lappa extract* in *premixtures* and *feedingstuffs* as the unambiguous determination of the *feed additive* added to the matrices is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the determination of *Arctium lappa extract* in *premixtures* and *feedingstuffs*.

***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.

***Identification/Characterisation of the feed additive (section 2.6.3 of the dossier - Annex II of Commission Regulation (EC) No 429/2008)***

An evaluation of corresponding methods of analysis is not considered necessary by the EURL.

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 recommends for official control for the determination of the proposed phytochemical marker *inulin* in the *feed additive* the analytical method described in the ring trial validated AOAC Official Method 997.08 based on Ion Exchange Chromatography coupled with Pulsed Amperometric Detection (IEC-PAD).

***Recommended text for the register entry (analytical method)***

For the determination of the selected phytochemical marker *inulin* in the *feed additive*:

- Ion exchange chromatography coupled with pulsed amperometric detection (IEC-PAD) - AOAC Official Method 997.08

#### 5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Arctium lappa extract (Great Burdock extract CoE 57)* 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, Reference SANTE\_E5\_FWD. APPL. 1831-0021-2018
- [2] \*Application form, Annex I, Submission No. 1288799753405-1382
- [3] \*Application, Proposal for Register Entry – Annex A
- [4] \*Technical dossier, Section II: II.1.3 Qualitative and quantitative composition
- [5] \*Technical dossier, Section II: II.2 Characterisation of the active substance(s)/agent(s)
- [6] \*Technical dossier, Section II: II.5.1 Proposed mode of use in animal nutrition
- [7] \*Technical dossier, Section II: II.6.1 Methods of analysis for the active substance
- [8] AOAC Official Method 997.08 Fructans in Food Products
- [9] \*Technical dossier, Section II: Annex II.1.03

\*Refers to Dossier no: FAD-2010-0301

#### 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.

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## 8. ACKNOWLEDGEMENTS

The following National Reference Laboratories contributed to this report:

- Państwowy Instytut Weterynaryjny, Pulawy (PL)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 — Labore Landwirtschaft, Nossen (DE)