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**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**

Acacia gum
(FAD-2010-0159; CRL/100146)



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Dossier related to: **FAD-2010-0159 - CRL/100146**

Name of Feed Additive: ***Acacia gum* E414**

Active Agent(s): **-**

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

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Date: **(EURL-FA)
5/12/2014**

Report approved by: **Christoph von Holst**
Date: **5/12/2014**

EXECUTIVE SUMMARY

In the current applications authorisation is sought under article 10(2) for *Acacia gum* under the 'category' / 'functional groups' 1(c), 1(d), 1(e) and 1(f) 'technological additives' / 'emulsifiers', 'stabilisers', 'thickeners' and 'gelling agents' 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 all animal species. The feed additive is a dried natural exudate obtained from the stems and branches of natural strains of *Acacia Senegal* Willdenow or *Acacia Seyal* belonging to the family Leguminosae. *Acacia gum* consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts. *Acacia gum* can be used in the form of flakes, granulates, powder and spraydried material. The Applicant stated that the purity criteria/specification set in Commission Regulation (EU) 231/2012 for the food additive are applicable also for the *feed additive* [3]. The *feed additive* is intended to be incorporated into *feedingstuffs* through *premixtures* with no recommended minimum or maximum inclusion levels.

For the characterisation of *Acacia gum* the Applicant refers to the Commission Regulation (EU) 231/2012 which requires a solubility test and the following quantitative assays: - loss on drying; - total ash; - acid insoluble ash; and - acid insoluble matter. These methods are described in the FAO JECFA Compendium for food additives. Furthermore, two European Pharmacopoeia monographs are available for the characterisation of crude and spray-dried *Acacia gums*. The two monographs are very similar, the main difference residing on loss on drying and insoluble matter characteristics. The monographs include also a test for viscosity.

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods for the characterisation of *Acacia gum* described in the European Pharmacopoeia monographs and the Commission Regulation (EU) 231/2012.

Since the accurate quantification of *Acacia gum* added to *premixtures* or *feedingstuffs* is not achievable experimentally the EURL cannot evaluate nor recommend any method for official control to quantify *Acacia gum* in *premixtures* or *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) is not considered necessary.

KEYWORDS

Acacia gum, technological additives, emulsifiers, stabilisers, thickeners, gelling agents, all animal species

1. BACKGROUND

In the current applications authorisation is sought under article 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) for *Acacia gum* under the 'category' / 'functional groups' 1(c), 1(d), 1(e) and 1(f) 'technological additives' / 'emulsifiers', 'stabilisers', 'thickeners' and 'gelling agents' according to the classification system of Annex I of Regulation (EC) No 1831/2003 [1,2]. Specifically, authorisation is sought for the use of the feed additive for all animal species [1,2].

The *feed additive* is a dried natural exudate obtained from the stems and branches of natural strains of *Acacia Senegal Willdenow* or *Acacia Seyal* belonging to the family *Leguminosae*. *Acacia gum* consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield galactose, arabinose, rhamnose and glucuronic acids. *Acacia gum* can be used in the form of flakes, granulates, powder and spraydried material [3].

The Applicant stated that the purity criteria/specification set in Commission Regulation (EU) 231/2012 for the food additive are applicable also for the *feed additive* [3]. The *feed additive* is intended to be incorporated into *feedingstuffs* through *premixtures* with no recommended minimum or maximum inclusion levels [2,3].

2. TERMS OF REFERENCE

In accordance with Article 5 of Regulation (EC) No 378/2005, as last amended by Regulation (EC) No 885/2009, 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 *Acacia gum* and their suitability to be used for official controls in the frame of the authorisation were evaluated.

3. EVALUATION

Identification /Characterisation of the feed additive

Qualitative and quantitative composition of impurities in the additive

When required by EU legislation, analytical methods for official control of undesirable substances in the additive (e.g. arsenic, cadmium, lead, mercury, *salmonella* spp, *E.coli* aflatoxin B1 and dioxins) are available from the respective European Union Reference Laboratories [4].

Description of the analytical methods for the determination of the active substance in feed additive, premixtures and feedingstuffs

For the characterisation of *Acacia gum* the Applicant refers to the Commission Regulation (EU) 231/2012 which requires a solubility test and the following quantitative assays: - loss on drying; - total ash; - acid insoluble ash; and - acid insoluble matter. These methods are described in the FAO JECFA Compendium for food additives [5,6]. Furthermore, two European Pharmacopoeia monographs are available for the characterisation of crude [7] and spray-dried [8] *Acacia gums*. The two monographs are very similar, the main difference residing on loss on drying and insoluble matter characteristics. The monographs include also a test for a viscosity. The Applicant suggested additional tests (i.e. viscosity, pH, mesh size) described in the European Pharmacopoeia [9].

For the determination of loss on drying, the sample (1 to 2 g) is placed in the oven at 105°C for 5h. The sample is weighed again after cooling to room temperature and the difference of the weights is calculated [5,6].

For determination of total ash a known quantity of sample (resulting about 20 mg of ash) is weighed in a tarred crucible and ignited at 550°C and kept there until free from carbon. The residue is weighed after cooling [5,6].

For determination of acid insoluble ash, the total ash is boiled with diluted HCl for 5 min, the insoluble matter is collected on a suitable ash-less filter, ignited at 800±25°C, cooled down and weighed. The percentage of acid-insoluble ash is calculated from the weight of the sample taken [5,6].

For the determination of acid insoluble matter content the sample (2 g) is added to diluted sulphuric acid. The mixture is heated for 6h, then filtered through Gooch crucible. The insoluble matter is dried at 105°C for 3h and weighed. [5,6].

The viscosity is determined using a suitable capillary viscometer at a room temperature by measuring the time required for the level of the liquid to drop from one mark to the other [9].

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods for the characterisation of *Acacia gum* described in the European Pharmacopoeia monograph and the Commission Regulation (EU) 231/2012.

Since the accurate quantification of *Acacia gum* added to *premixtures* or *feedingstuffs* is not achievable experimentally the EURL cannot evaluate nor recommend any method for official control to quantify *Acacia gum* in *premixtures* or *feedingstuffs*. Eventhough the Applicant mentioned an AOAC method for the quantification of total dietary fiber [10], no validation/verification data were provided proving the applicability of the method to the quantification of *Acacia gum* in *premixtures* or *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) is not considered necessary.

4. CONCLUSIONS AND RECOMMENDATIONS

In the frame of this authorisation the EURL recommends for official control the methods described in the European Pharmacopoeia and in the Commission Regulation (EU) 231/2012 for characterisation of *Acacia gum* (*feed additive*).

Since the accurate quantification of *Acacia gum* added to *premixtures* or *feedingstuffs* is not achievable experimentally, the EURL cannot evaluate nor recommend any method for official control to quantify *Acacia gum* in *premixtures* or *feedingstuffs*.

Recommended text for the register entry (analytical method)

For the characterisation of *Acacia gum* (*feed additive*):

- European Pharmacopoeia monograph 0307 or 0308, and
- Commission Regulation (EU) No 231/2012 and the corresponding tests in the FAO JECFA Compendium

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Acacia gum* 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 SANCO/G1: Forw. Appl. 1831/0053-2013
- [2] *Application, Proposal for Register Entry
- [3] *Technical dossier, Section II: Identity, characterisation and conditions of use of the additive; methods of analysis
- [4] Commission Regulation (EC) No 776/2006 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards to Community Reference Laboratories
- [5] FAO JECFA Combined Compendium of Food Additive Specifications, 'Gum Arabic', Monograph No. 1 (2006)
<http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-219.pdf>
(last visited on 17/11/2014)
- [6] FAO JECFA Combined Compendium for Food Additive Specifications - Analytical methods, test procedures and laboratory solutions used by and referenced in the food

additive specifications, Vol. 4

<http://www.fao.org/docrep/009/a0691e/a0691e00.htm> (last visited on 17/11/2014)

- [7] European Pharmacopoeia monograph – Ph.Eur. 6.3 01/2009:0307
- [8] European Pharmacopoeia monograph – Ph.Eur. 6.3 01/2009:0308
- [9] European Pharmacopoeia, General chapters, Methods of Analysis
- [10] AOAC Official Method 985.29, Total dietary fibre determination

*Refers to Dossier no: FAD-2010-0159

7. RAPPORTEUR LABORATORY & NATIONAL REFERENCE LABORATORIES

The Rapporteur Laboratory for this evaluation was European Union Reference Laboratory for Feed Additives, IRMM, 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 (EC) No 885/2009.

8. ACKNOWLEDGEMENTS

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- Państwowy Instytut Weterynaryjny, Puławy (PL)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 - Labore Landwirtschaft, Nossen (DE)¹
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- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes (FR)

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