



EUROPEAN COMMISSION

DIRECTORATE GENERAL
JOINT RESEARCH CENTRE

Directorate D: Institute for Reference Materials and Measurements
European Union Reference Laboratory for Feed Additives

JRC.D.5/SFB/CvH/JK/mds/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**

Tragacanth gum
(FAD-2010-0392; CRL/100311)



**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-2010-0392 - CRL/100311**

Name of Feed Additive: ***Tragacanth gum* E413**

Active Agent(s): **-**

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

Report prepared by: **Johanna Keltti**

Report checked by: **Piotr Robouch and Zigmantas Ezerskis**
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 *Tragacanth gum* under the 'category' / 'functional groups' 1(c), 1(d), 1(e) and 1(f) 'technological additives' / 'emulsifiers', 'stabilisers', 'thickeners', '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 exudate obtained from the stems and branches of natural strains of *Astragalus gummifer Labillardiere* or other Asiatic species of *Astragalus* belonging to the family *Leguminosae*. Powdered *Tragacanth gum* is white to pale yellow or pinkish brown by colour. *Tragacanth gum* consists mainly of high molecular weight polysaccharides (galactoarabans and acidic polysaccharides). The Applicant stated that the purity criteria/specification set in Commission Regulation (EU) 231/2012 for the food additive are also applicable for the *feed additive*. The *feed additive* is intended to be incorporated into *feedingstuffs* through *premixtures* with no recommended minimum or maximum inclusion levels.

For the characterisation of *Tragacanth 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, the presence or absence of several gum constituents (e.g . arabinose, xylose, fucose, galactose, galacturonic acid, mannose, karaya and glucuronic acid) is tested according to the *Tragacanth gum* monographs of the European Pharmacopoeia and the FAO JECFA Compendium. Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods for the characterisation of *Tragacanth gum* described in the European Pharmacopoeia monograph and the Commission Regulation (EU) 231/2012.

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

Tragacanth 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 *Tragacanth gum* under the 'category' / 'functional groups' 1(c), 1(d), 1(e) and 1(f) 'technological additives' / 'emulsifiers', 'stabilisers', 'thickeners', '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 exudate obtained from the stems and branches of natural strains of *Astragalus gummifer Labillardiere* or other Asiatic species of *Astragalus* belonging to the family *Leguminosae*. Powdered *Tragacanth gum* is white to pale yellow or pinkish brown by colour. *Tragacanth gum* consists mainly of high molecular weight polysaccharides (galactoarabans and acidic polysaccharides) which, on hydrolysis, yield galacturonic acid, galactose, arabinose, xylose and fucose [2,3].

The Applicant stated that the purity criteria/specifications set in Commission Regulation (EU) 231/2012 for the food additive are also applicable 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 *Tragacanth 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 *Tragacanth gum* the Applicant submitted 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, the presence or absence of several gum constituents (e.g . arabinose, xylose, fucose, galactose, galacturonic acid, mannose, karaya and glucuronic acid) are tested according to the *Tragacanth gum* monographs of the European Pharmacopoeia and the FAO JECFA Compendium [7,6]. The Applicant suggested an additional viscosity test described in the European Pharmacopoeia [8].

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 tared 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].

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

Since the accurate quantification of *Tragacanth gum* added to *premixtures* or *feedingstuffs* is not achievable experimentally the EURL cannot evaluate nor recommend any method for official control to quantify *Tragacanth gum* in *premixtures* or *feedingstuffs*. Eventhough the Applicant mentioned a gas chromatography method originally developed for food matrices [9] and an AOAC method for the quantification of total dietary fiber [10], no validation/verification data were provided proving the applicability of these methods for the quantification of *Tragacanth 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 *Tragacanth gum* (*feed additive*).

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

Recommended text for the register entry (analytical method)

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

- European Pharmacopoeia monograph 0532, 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 *Tragacanth 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. 1831/0051-2013
- [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, 'Tragacanth gum', Monograph No. 1 (2006)
<http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-471.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 01/2009:0532
- [8] European Pharmacopoeia, General chapters, Methods of Analysis
- [9] J. F. Lawrence, J. R. Iyengar. Journal of Chromatography, 350 (1985) 237-244
- [10] AOAC Official Method 985.29, Total dietary fiber determination

*Refers to Dossier no: FAD-2010-0392

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

The following National Reference Laboratories contributed to this report:

- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Państwowy Instytut Weterynaryjny, Puławy (PL)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 - Labore Landwirtschaft, Nossen (DE)¹
- Univerza v Ljubljani, Veterinarska fakulteta. Nacionalni veterinarski inštitut, En ota za patologijo prehrane in higieno okolja, Ljubljana (SI)
- Thüringer Landesanstalt für Landwirtschaft (TLL), Abteilung Untersuchungswesen, Jena (DE)
- Schwerpunktlabor Futtermittel des Bayerischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim (DE)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes (FR)

¹ Name and address according to Regulation (EC) No 885/2009: Sächsische Landesanstalt für Landwirtschaft. Fachbereich 8 – Landwirtschaftliches Untersuchungswesen, Leipzig