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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

Locust Bean Gum (FAD-2010-0360; CRL/100317)



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-2010-0360 - CRL/100317**

Name of Product: Locust Bean Gum

Active Agent (s):

Rapporteur Laboratory: European Union Reference Laboratory for

Feed Additives (EURL-FA)

Geel, Belgium

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Date: **24/06/2014**

Report approved by: **Christoph von Holst**

Date: **25/06/2014**



EXECUTIVE SUMMARY

In the current application authorisation is sought under article 10(2) for *Locust Bean 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.

Locust Bean Gum is white-to-brown powder consisting of a minimum of 75 % of galactomannan with a galactose/mannose ratio close to 1:3.9. The feed additive is intended to be incorporated directly into feedingstuffs with proposed maximum inclusion level of 1 % (10 g/kg) of Locust Bean Gum in the complete feedingstuffs.

For the characterisation of *Locust Bean Gum* in the *feed additive* the Applicant proposed the internationally recognised FAO JECFA monographs for food additives, recommended by Commission Directive 2008/84/EC, where identification is based on: - positive test for galactose and manose; - microscopic examination; - solubility; - loss on drying; - protein content; and - acid insoluble matter content, while the quantification of the galactomannan content is determined substracting the values of loss on drying, protein and acid insoluble matter contents from the initial weight of the *feed additive*.

Even though no performance characteristics are provided, the EURL recommends for official control the methods described in the FAO JECFA monographs - as recommended by Commission Directive 2008/84/EC - to characterise *Locust Bean Gum* in the *feed additive*.

The Applicant provided no experimental data or any analytical methods for the quantification of *Locust Bean Gum* in *feedingstuffs*, as the accurate determination of *Locust Bean Gum* in *feedingstuffs* is not achievable experimentally. Therefore the EURL cannot evaluate nor recommend any method for official control to quantify *Locust Bean Gum* in *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

Locust Bean Gum, galactomannan, galactose, mannose, technological additives, emulsifiers, stabilisers, thickeners, gelling agents, all animal species



1. BACKGROUND

In the current application authorisation is sought under article 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) for *Locust Bean 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]. Specifically, authorisation is sought for the use of the *feed additive* for all animal species [1,2].

Locust Bean Gum is white-to-brown powder produced from endosperm of the seeds of Carob tree (Ceretonia siliqua) belonging to the family Leguminosae. The feed additive consists of a minimum of 75 % of galactomannan with a galactose/mannose ratio close to 1:3.9 [3]. The feed additive is intended to be incorporated directly into feedingstuffs with proposed maximum inclusion level of 1 % (10 g/kg) of Locust Bean Gum in complete feedingstuffs [2].

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 (EFSA) for each application or group of applications. For this particular dossier, the methods of analysis submitted in connection with *Locust Bean 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, mycotoxins 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 and feedingstuffs

For the characterisation of *Locust Bean Gum* in the *feed additive* the Applicant submitted the internationally recognised FAO JECFA monographs for food additives [5,6], recommended by Commission Directive 2008/84/EC, where <u>identification</u> is based on: - positive test for galactose and manose; - microscopic examination; - solubility; - loss on drying; - protein content; and - acid insoluble matter content, while the <u>quantification</u> of the galactomannan content is determined substracting the values of loss on drying, protein and acid insoluble matter contents from the initial weight of the *feed additive* [3].

For the determination of loss on drying, the sample of 1 to 2 g is placed in empty glass-stoppered bottle with known weight (stopper included) and put in the drying chamber at 105 °C for 5h. Upon opening the chamber the bottle is closed promptly, adjusted to room temperature in a desiccator and weighed; the difference of the weights is loss on drying [5].

For the determination of acid insoluble matter content the sample of 2 g is contained in diluted sulphuric acid. The mixture is heated for 6 h and filtered through suitable acid filter, which is pre-dried and weighed; the filter is dried at 105° for 3 h and weighed. The difference of the weights is acid insoluble matter content [5].

The protein content in the sample is calculated by multiplying by 6.25 the nitrogen content determined using Kjeldahl method [5,6].

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods described in the FAO JECFA monographs - as recommended by Commission Directive 2008/84/EC to characterise *Locust Bean Gum* in the *feed additive*.

The Applicant provided no experimental data or any analytical methods for the quantification of *Locust Bean Gum* in *feedingstuffs*, as the accurate determination of *Locust Bean Gum* in *feedingstuffs* is not achievable experimentally. Therefore the EURL cannot evaluate nor recommend any method for official control to quantify *Locust Bean Gum* in *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 of *Locust Bean Gum* in the *feed additive*, the analytical methods recommended by Commission Directive 2008/84/EC and described in the FAO JECFA monographs.

The Applicant provided no experimental data or any analytical methods for the quantification of *Locust Bean Gum* in *feedingstuffs*, as the accurate determination of *Locust Bean Gum* in *feedingstuffs* is not achievable experimentally. Therefore the EURL cannot evaluate nor recommend any method for official control to quantify *Locust Bean Gum* in *feedingstuffs*.

Recommended text for the register entry (analytical method)

For the determination of *Locust Bean Gum* in the *feed additive*:

- FAO JECFA Monograph 'Carob Bean Gum' as referred in Commission Directive 2008/84/EC

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Locust Bean 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, Ref.: SANCO/G1:Forw.Appl.1831/0054-2013
- [2] *Application, Proposal for Register Entry Annex A
- [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 for Food Additive Specifications Analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications, Monographs No. 1, Vol. 4
 http://www.fao.org/docrep/009/a0691e/a0691e00.htm
 (last visited on 12/05/2014)
- [6] FAO JECFA Combined Compendium of Food Additive Specifications, 'Carob Bean Gum', Monograph No. 5 (2008)

 http://www.fao.org/ag/agn/jecfa-additives/specs/monograph5/additive-110-m5.pdf
 (last visited on 12/05/2014)

^{*}Refers to Dossier no: FAD-2010-0360



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:

- Sachgebiet Futtermittel des Bayrischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim (DE)¹
- Fødevarestyrelsen, Ringsted (DK)²
- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 -Labore Landwirtschaft, Nossen (DE)³

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