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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

Gellan gum

(FAD-2018-0075; CRL/180049)

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-2018-0075 - CRL/180049**
Name of Product:	***Gellan gum E418***
Active Agent (s):	**-**
Rapporteur Laboratory:	**European Union Reference Laboratory for Feed Additives (EURL-FA)** **JRC Geel, Belgium**
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Report checked by: Date:	**Stefano Bellorini** **19/03/2019**
Report approved by: Date:	**Christoph von Holst** **19/03/2019**

EXECUTIVE SUMMARY

In the current applications authorisation is sought under Article 4(1) for *gellan gum* under the 'category'/'functional groups' 1(d), 1(e) and 1(f) 'technological additives'/'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 cats and dogs.

The *feed additive* is a purified, dried and milled high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate by the microbe *Sphingonomas elodea.* Commercial *gellan gum* is available for food and feed in two forms; so-called high acyl *gellan gum* and low acyl *gellan gum.* The Applicant stated that the purity criteria/specifications of the *feed additive* are as set in Commission Regulation (EU) No 231/2012 on the food additive. *Gellan gum* is intended to be incorporated directly into *feedingstuffs* with no recommended minimum or maximum inclusion levels.

For the characterisation of *gellan gum* the Applicant proposed the tests stated in the Commission Regulation (EU) No 231/2012 and in the specific JECFA Monograph. These methods are described in the FAO JECFA Compendium for food additives. The EURL recommends therefore for official control the above mentioned methods for the characterisation of *gellan gum.*

As the accurate quantification of *gellan gum* added to *feedingstuffs* is not achievable experimentally, the EURL cannot evaluate nor recommend any method for official control to quantify *gellan 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, as last amended by Regulation (EU) 2015/1761) is not considered necessary.

KEYWORDS

Gellan gum, technological additives, stabilisers, thickeners, gelling agents, cats and dogs

1. BACKGROUND

In the current applications authorisation is sought under Article 4(1) (authorisation of a *feed additive*) for *gellan gum* under the 'category'/'functional groups' 1(d), 1(e) and 1(f) 'technological additives'/'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 cats and dogs [1-2].

The *feed additive* is a purified, dried and milled high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate by the microbe *Sphingonomas elodea*. Commercial *gellan gum* is a 100 % pure product without any additional ingredient and is available for food and feed in two commercial forms: so-called high acyl *gellan gum* and low acyl *gellan gum* [3].

The Applicant stated that the purity criteria/specifications of *gellan gum* set in Commission Regulation (EU) No 231/2012 on the food additive are also applicable for the *feed additive* [3-4]. The *feed additive* is intended to be incorporated directly into *feedingstuffs* 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 (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 *gellan gum* 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 characterisation of *gellan gum* the Applicant proposed the tests indicated in Commission Regulation (EU) No 231/2012 and in the JECFA Monograph for *gellan gum* [4-5] which require a solubility test and a gel test with calcium and sodium ions for identification and the following quantitative determination: loss on drying, nitrogen, lead, residual solvents and additional microbiological criteria. Some of the methods are described in a different FAO JECFA volume [6].

The EURL recommends for official control the above mentioned methods for the characterisation of *gellan gum* as described in the JECFA monograph and in the Commission Regulation (EU) No 231/2012.

In addition the Applicant submitted two analytical methods based on high pressure capillary ion chromatography (HPIC) with mass spectrometry detection and with pulsed amperometric detection, respectively, for the determination of high acyl or low acyl *gellan gum* in

feedingstuffs [7]. However, no validation and/or verification data were provided proving the applicability of these methods for the quantification of *gellan gum* in *feedingstuffs*.

As the accurate quantification of *gellan gum* added to *feedingstuffs* is not achievable experimentally, the EURL cannot evaluate nor recommend any method for official control to quantify *gellan gum* in f*eedingstuffs*.

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)

The 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 the methods described in the JECFA monograph and in Commission Regulation (EU) No 231/2012 for the characterisation of *gellan gum* (*feed additive*).

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

Recommended text for the register entry (analytical method)

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

- JECFA monograph 16, and
- Commission Regulation (EU) No 231/2012 and the corresponding tests described 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 *gellan 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 SANTE/E5: FORW. APPL. 1831-0072-2018 & Annex I Submission No: 1537191784742-2288

[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 (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

[5] FAO JECFA Combined Compendium of Food Additive Specifications, 'Gellan gum', Monograph No. 16 (2014) http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph16/additive-199-m16.pdf

[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/3/a-i4144e.pdf

[7] *Technical dossier, Annexes II_2.6

*Refers to Dossier no: FAD-2018-0075

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

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