EUROPEAN COMMISSION
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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

Xanthan Gum
(FAD-2010-0250; CRL/100199)

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-2010-0250 - CRL/100199**
Name of Product:	***Xanthan Gum***
Active Agent (s):	**Xanthan Gum**
Rapporteur Laboratory:	**European Union Reference Laboratory for Feed Additives (EURL-FA)** **Geel, Belgium**
Report prepared by:	**Johanna Keltti**
Report checked by: Date:	**Piotr Robouch (EURL-FA)** **17/9/2014**
Report approved by: Date:	**Christoph von Holst** **18/9/2014**

EXECUTIVE SUMMARY

In the current applications authorisation is sought under article 10(2) for *Xanthan Gum*, under the 'category' / 'functional groups' 1(d) and 1(e) 'technological additives' / 'stabilisers' and 'thickeners' 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.

Xanthan gum is typically added to influence and stabilize the texture of the wet part of canned feed e.g. for dog or cat. The Applicant stated that the purity criteria set in the Commission Regulation (EU) 231/2012 for the food additive apply also for the *feed additive.* The applicant did not specify minimum or maximum levels of the product in feed, but states that the levels applied are comparable to the Xanthan gum levels in food for human consumption, ranging from 0.01 to 1.0% w/w.

For the characterisation of *Xanthan gum* the Applicant submitted two internationally recognised monographs (European Pharmacopoeia and FAO JECFA monograph for food additive '*Xanthan gum*'). Identification is based on gel formation with Locust bean gum, while characterisation is based on the following quantitative assays: - determining the carbon dioxide yields corresponding to the concentration/purity of *Xanthan gum*; - pyruvic acid assay; - loss on drying; and - total ash. The resulting values are to be compared against the authorised target values. Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods described in the FAO JECFA monographs and recommended by Commission Regulation (EU) 231/2012 to characterise *Xanthan gum.*

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

Xanthan Gum, technological additives, stabilisers, thickeners, all 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 *Xanthan Gum*, under the 'category' / 'functional groups' 1(d) and 1(e) 'technological additives' / 'stabilisers' and 'thickeners' 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].

Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with natural strains of Xanthomonas campestris. It is a cream-coloured powder and contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid [3]. The Applicant stated that the purity criteria set in Commission Regulation (EU) 231/2012 for the food additive apply also for the *feed additive* [3].

Xanthan gum is typically added to influence and stabilize the texture of the wet part of canned feed e.g. for dog or cat. It also generates viscosity for filling and helps keeping insoluble materials such as minerals and chunks in suspension. The applicant did not specify minimum or maximum levels but states that the levels applied are comparable to the *Xanthan gum* levels in food for human consumption, ranging from 0.01 to 1.0 % w/w [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 *Xanthan 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, aflatoxin B1 and dioxins) are available from the respective European Union Reference Laboratories [4].

For the analysis of process residues (i.e. nitrogen, ethanol and propanol) and microbiological purity criteria (i.e. *salmonella spp*, *E. coli*, total plate counts and yeasts & moulds) the Applicant submitted the analytical tests described in the FAO JECFA Compendium [5].

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

For the characterisation of *Xanthan gum* the Applicant submitted two internationally recognised monographs from the European Pharmacopoeia [6] and from the FAO JECFA Compendium [5], the latter being recommended by Commission Regulation (EU) 231/2012.

Identification is based on gel formation with Locust bean gum. The *feed additive* is further characterised using the following quantitative assays: - determination of the carbon dioxide yields corresponding to the concentration/purity of *Xanthan gum;* - pyruvic acid assay; - loss on drying; and - total ash. The resulting values are to be compared against the authorised target values. The experimental protocols for generic tests are provided in the FAO JECFA Compendium of methods and in general chapters of European Pharmacopoeia [7,8].

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

Since the accurate quantification of *Xanthan gum* added to *feedingstuffs* is not achievable experimentally the EURL cannot evaluate nor recommend any method for official control to quantify *Xanthan gum* in *feedingstuffs.* However, the Applicant suggested an indirect analytical method, based on spectrophotometry, for the quantification of the minimum content of *Xanthan gum* in the *feedingstuffs* [3] – without providing any experimental data.

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 characterisation tests described in the FAO JECFA monograph and recommended by Commission Regulation (EU) 231/2012.

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

Recommended text for the register entry (analytical method)

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

- FAO JECFA Monograph *Xanthan gum,* as referred in Commission Regulation (EU) 231/2012

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Xanthan 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. 1831/0052-2013

[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, '*Xanthan gum'*, Monograph No. 1 (2006)
http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-487.pdf

[6] European Pharmacopoeia monograph – Ph.Eur. 6.3 01/2009/1277

[7] 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

[8] European Pharmacopoeia, General chapters, Methods of Analysis

*Refers to Dossier no: FAD-2010-0250

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:

- Fødevarestyrelsen, Ringsted (DK)[1]
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Państwowy Instytut Weterynaryjny, Puławy (PL)
- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes (FR)

[1] Name and address according to Regulation (EC) No 885/2009: Plantedirektoratet, Laboratorium for Foder og Gødning, Lyngby