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**European Union Reference Laboratory for Feed Additives**

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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**

**Agar**  
*(FAD-2010-0208; CRL/100196)*





**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-2010-0208 - CRL/100196**

Name of Product: ***Agar***

Active Agent (s): **Agar (E 406)**

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

Report prepared by: **Johanna Keltti**

Report checked by: **Piotr Robouch (EURL-FA)**  
Date: **20/06/2014**

Report approved by: **Christoph von Holst**  
Date: **08/07/2014**

## EXECUTIVE SUMMARY

In the current application authorisation is sought under article 10(2) for *Agar* 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 pets and other non-food producing animals.

The *feed additive* is a solid preparation in the form of powder, agglutinated strips, cut, flaked or granulated. It is intended to be incorporated directly into *feedingstuffs* and in *water*. The applicant did not specify minimum or maximum levels but states that the typical level of use may be up to 2% by weight of the wet final product.

For the characterisation of the *feed additive* (*Agar*) the Applicant submitted the internationally recognised FAO JECFA monographs for food additives, recommended by Commission Directive 2008/84/EC, which is based on: - solubility; - gel formation with water; - microscopic examination; and - two precipitate formation tests: with ammonium sulphate and with lead acetate solutions and the determination of the threshold gel concentration, which should not be higher than 0.25%. Furthermore, purity is determined applying the following tests: - water absorption; - loss on drying; - total ash; - acid-insoluble ash; and - foreign insoluble matter.

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 the *feed additive* (*Agar*).

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

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

*Agar*, technological additives, emulsifiers, stabilisers, thickeners, gelling agents, pets and other non-food producing animals

## 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 *Agar* 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 pets and other non-food producing animals [1,2].

The *Agar* is obtained from marine algae's of the seaweed class Rhodophyceae which grow on rocks situate just below low-tide level [3]. *Agar* belongs to the group of polysaccharides and consists primarily of D- and L-galactose units.

The *feed additive* is a solid preparation in the form of powder, agglutinated strips, cut, flaked or granulated. It is intended to be incorporated directly into *feedingstuffs* and in *water*. The applicant did not specify minimum or maximum levels but states that the typical level of use may be up to 2% by weight of the wet final product [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 *Agar* 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]

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

For the characterisation of the *feed additive (Agar)* the Applicant submitted the internationally recognised FAO JECFA monographs for food additives [5,6], recommended by Commission Directive 2008/84/EC, which is based on: - solubility; - gel formation with water; - microscopic examination; and - two precipitate formation tests: with ammonium sulphate and with lead acetate solutions and the determination of the threshold gel concentration, which should not be higher than 0.25% [3]. Furthermore, purity is determined applying the following tests: - water absorption; - loss on drying; - total ash; - acid-insoluble ash; and - foreign insoluble matter.

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 the *feed additive (Agar)*.

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

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 *Agar* (the *feed additive*), the analytical methods recommended by Commission Directive 2008/84/EC and described in FAO JECFA monographs.

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

***Recommended text for the register entry (analytical method)***

For the determination of *Agar* in the *feed additive*:

- FAO JECFA Monograph 'Agar' 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 *Agar* 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. 1831/0043-2013
- [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 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>
- [6] FAO JECFA Combined Compendium of Food Additive Specifications, 'Agar', Monograph No. 1 (2006)  
<http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-008.pdf>

\*Refers to Dossier no: FAD-2010-0208

## 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.

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## 8. ACKNOWLEDGEMENTS

The following National Reference Laboratories contributed to this report:

- Fødevarestyrelsen, Ringsted (DK)<sup>1</sup>
- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Univerza v Ljubljani, Veterinarska fakulteta. Nacionalni veterinarski inštitut, En ota za patologijo prehrane in higieno okolja, Ljubljana (SI)
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Sachgebiet Futtermittel des Bayrischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim (DE)<sup>2</sup>
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 - Labore Landwirtschaft, Nossen (DE)<sup>3</sup>
- Centre wallon de Recherches agronomiques (CRA-W), Gembloux (BE)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Państwowy Instytut Weterynaryjny, Puławy (PL)

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<sup>2</sup> Name and address according to Regulation (EC) No 885/2009: Schwerpunktlabor Futtermittel des Bayerischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim

<sup>3</sup> Name and address according to Regulation (EC) No 885/2009: Sächsische Landesanstalt für Landwirtschaft. Fachbereich 8 – Landwirtschaftliches Untersuchungswesen, Leipzig