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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**

Vermiculite
(FAD-2010-0128; CRL/100161)



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in connection with the Application for Authorisation of a
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Dossier related to: **FAD-2010-0128; CRL/100161**

Name of Product:

Active Agent (s): **Vermiculite**

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

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Report checked by: **Piotr Robouch (EURL-FA)**
Date: **20/04/2015**

Report approved by: **Christoph von Holst**
Date: **21/05/2015**

EXECUTIVE SUMMARY

In the current application authorisation is sought under article 10(2) for *vermiculite*, under the category/functional groups 1(g) and 1(i) 'technological additives/' 'binders' and 'anticaking agents', according to the classification system of Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the *feed additive* for pigs, poultry, bovines, sheep, goats, rabbits, horses.

Vermiculite is a soft phyllosilicate mineral which expands after thermal treatment producing an accordion-like lightweight grey to brown product. It is a magnesium aluminium iron silicate, consisting of SiO₂ (ca. 35-45%), MgO (ca. 20-40%), Al₂O₃ (ca. 7-15%) and Fe₂O₃ (ca. 10 %). The *feed additive* is intended to be used directly in *feedingstuffs*. The Applicant proposed a maximum inclusion level of 5 % *feed additive* in complete *feedingstuffs*.

For the characterisation of the *feed additive* the Applicant submitted an X-Ray Fluorescence Spectroscopy (XRFS) method accredited by UKAS. Even though no performance characteristics are provided, the EURL recommends for official control the method based on X-Ray Fluorescence Spectroscopy (XRFS) for the characterisation of *vermiculite*.

The Applicant provided no experimental data or any analytical method for the determination of the *vermiculite* in *feedingstuffs* as the unambiguous determination of the *feed additive* added to the matrix is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the direct determination of *vermiculite* 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

Vermiculite, technological additives, binders, anticaking agents, pigs, poultry, bovines, goats, rabbits, horses.

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 *vermiculite*, under the category/functional groups 1(g) and 1(i) 'technological additives/' 'binders' and 'anticaking agents', according to the classification system of Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the *feed additive* for pigs, poultry, bovines, sheep, goats, rabbits, horses [1,2].

Vermiculite is a soft phyllosilicate mineral which expands under thermal treatment producing an accordion-like lightweight grey to brown product. It is a magnesium aluminium iron silicate consisting of SiO₂ (ca. 35-45%), MgO (ca. 20-40%), Al₂O₃ (ca. 7-15%) and Fe₂O₃ (ca. 10 %) [3].

The *feed additive* is intended to be used directly in *feedingstuffs*. The Applicant proposed a maximum inclusion level of 5 % *feed additive* in complete *feedingstuffs* [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 *vermiculite* 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].

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* the Applicant submitted method based on X-Ray Fluorescence Spectroscopy (XRFS), accredited by UKAS [5] and reported the following [6]:

SiO₂ ranging from 38.8 to 40.1 %;
MgO ranging from 22.8 to 24.4 %;
Al₂O₃ ranging from 8.8 to 9.7 %;
Fe₂O₃ ranging from 7.9 to 8.2 %; and
K₂O ranging from 5.0 to 6.5 %.

However, the applicant did not provide any elemental composition of the major components.

Even though no performance characteristics are provided, the EURL recommends for official control the method based on X-Ray Fluorescence Spectroscopy (XRFS) for the characterisation of *vermiculite*.

The Applicant provided no experimental data or any analytical method for the determination of the *vermiculite* in *feedingstuffs* as the unambiguous determination of the *feed additive* added to the matrix is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the direct determination of *vermiculite* 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

The EURL recommends for official control the method based on X-Ray Fluorescence Spectroscopy (XRFS) for the characterisation of *feed additive*.

As the quantification of *vermiculite* added to *feedingstuffs* is not achievable experimentally, the EURL cannot recommend any method for official control in this matrix.

Recommended text for the register entry (analytical method)

Characterisation of *the feed additive*:

- X-Ray Fluorescence Spectroscopy (XRFS)

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *vermiculite* 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. 1831/0033-2014
 - [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] *Technical dossier, Section II, Attachment 9
 - [6] *Technical dossier, Section II, Attachment 8
- *Refers to Dossier no: FAD-2010-0128

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:

- 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)
- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes (FR)
- Państwowy Instytut Weterynaryjny, Puławy (PL)
- Thüringer Landesanstalt für Landwirtschaft (TLL), Abteilung Untersuchungswesen, Jena (DE)
- RIKILT-Instituut voor Voedselveiligheid, Wageningen (NL)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft, Freistaat Sachsen, Nossen¹ (DE)
- Univerza v Ljubljani, Veterinarska fakulteta. Nacionalni veterinarski inštitut, Enota za patologijo prehrane in higieno okolja, Ljubljana (SI)

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