



ADOPTED: 25 May 2020

doi: 10.2903/j.efsa.2020.6160

## Safety and efficacy of vermiculite as a feed additive for pigs, poultry, bovines, sheep, goats, rabbits and horses

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Kos Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Georges Bories, Jürgen Gropp, Carlo Nebbia, Matteo Lorenzo Innocenti and Gabriele Aquilina

### Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on vermiculite as a feed additive for pigs, poultry, bovines, sheep, goats, rabbits and horses. Vermiculite, which is a magnesium aluminium iron silicate, is intended for use as a technological additive (functional groups: binders and anticaking agents) in premixtures and feedingstuffs for pigs, poultry, bovines, sheep, goats, rabbits and horses, with no proposed minimum or maximum concentration. The applicant reported a maximum inclusion level, derived from the use of the additive in premixtures of preservatives, of about 50,000 mg/kg complete feed, and suggested typical inclusion levels in complete feedingstuffs below 10,000 mg/kg. The FEEDAP Panel could not conclude on the safety of vermiculite for the target species and the users. The additive is considered safe for the consumer and the environment at the proposed conditions of use. In the absence of data, the Panel could not conclude on the efficacy of vermiculite as a pellet binder or as an anticaking agent.

© 2020 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

**Keywords:** technological additive, binder, anticaking agent, vermiculite, safety, efficacy, feed

**Requestor:** European Commission

**Question number:** EFSA-Q-2014-00459

**Correspondence:** [feedap@efsa.europa.eu](mailto:feedap@efsa.europa.eu)

**Panel members:** Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Kos Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

**Suggested citation:** EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Kos Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Bories G, Gropp J, Nebbia C, Innocenti ML and Aquilina G, 2020. Scientific Opinion on the safety and efficacy of vermiculite as a feed additive for pigs, poultry, bovines, sheep, goats, rabbits and horses. *EFSA Journal* 2020;18(6):6160, 10 pp. <https://doi.org/10.2903/j.efsa.2020.6160>

**ISSN:** 1831-4732

© 2020 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs License](https://creativecommons.org/licenses/by/4.0/), which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.



## Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference.....	4
1.2. Additional information.....	4
2. Data and methodologies.....	4
2.1. Data.....	4
2.2. Methodologies.....	4
3. Assessment.....	5
3.1. Characterisation.....	5
3.1.1. Characterisation of the additive.....	5
3.1.2. Purity.....	5
3.1.3. Physical state of the product.....	6
3.1.4. Stability and homogeneity.....	6
3.1.5. Conditions of use.....	6
3.2. Safety.....	7
3.2.1. Safety for the target species.....	7
3.2.2. Safety for the consumer.....	7
3.2.3. Safety for user.....	7
3.2.4. Safety for the environment.....	7
3.3. Efficacy.....	7
4. Conclusions.....	8
5. Documentation as provided to EFSA/Chronology.....	8
References.....	8
Abbreviations.....	9
Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for vermiculite.....	10

## 1. Introduction

### 1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from Pull Rhenen<sup>2</sup> for re-evaluation of the product vermiculite, when used as a feed additive for pigs, poultry, bovines, sheep, goats, rabbits and horses (category: technological additive; functional group: g) binders; i) anticaking agents).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 4 March 2015.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product vermiculite, when used under the proposed conditions of use (see Section 3.1.5).

### 1.2. Additional information

The additive under assessment is vermiculite, a magnesium aluminium iron silicate. The additive is authorised<sup>3</sup> for use as a technological additive in feedingstuffs for all animal species with no minimum and maximum content. It has not been previously assessed by EFSA as feed additive.

## 2. Data and methodologies

### 2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier<sup>4</sup> in support of the authorisation request for the use of vermiculite as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers and other scientific reports to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active substance in animal feed. The Executive Summary of the EURL report can be found in Annex A.<sup>5</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of vermiculite is in line with the principles laid down in Regulation (EC) No 429/2008<sup>6</sup> and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012a), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011), Technical Guidance for

<sup>1</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

<sup>2</sup> Pull Rhenen, Utrechtsestraatweg 222, 3911 TX, Rhenen, Netherlands.

<sup>3</sup> Commission Regulation (EC) No 2439/1999 of 17 November 1999.

<sup>4</sup> FEED dossier reference: FAD-2010-0128.

<sup>5</sup> The full report is available on the EURL website: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0128?search&form-return>

<sup>6</sup> Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p.

assessing the safety of feed additives for the environment (EFSA, 2008), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b).

### 3. Assessment

The additive under assessment is vermiculite, a clay mineral classified as a magnesium aluminium iron silicate.

The applicant is seeking an authorisation for the use of the product as a technological additive (functional group: (g) binders and (i) anticaking agents) in feedingstuffs for pigs, poultry, bovines, sheep, goats, rabbits and horses.

#### 3.1. Characterisation

##### 3.1.1. Characterisation of the additive

The additive is a grey to brown granular product characterised by a sheet-like structure. It is a soft phyllosilicate mineral which expands after thermal treatment producing an accordion-like lightweight grey to brown product. The production process is based on a mechanical process only, with no chemicals used during the manufacturing. Vermiculite is obtained by mining, followed by crushing, grinding, drying and sizing. The granular vermiculite is then heated for a few seconds to temperatures above 600°C, leading to the sudden evaporation of the combined water. The granules expand and extend in length, in a process called exfoliation, reaching dimensions typically of > 100 µm. The exfoliated structure gives vermiculite a high capacity to absorb liquids. Depending on the size of the particles, different commercial products are available. According to the applicant, only two types of vermiculite (called micron grade and superfine grade) are used in animal nutrition.

The product is specified to contain 100% vermiculite, a magnesium aluminium iron silicate. One batch of the additive was analysed with X-ray diffraction (XRD),<sup>7</sup> confirming the identity of the additive and the specification. The same analysis showed the absence of crystalline silica in the additive. The additive (four analysis, each of them including two batches of micron grade and superfine grade vermiculite)<sup>8</sup> was also characterised by its elemental composition, determined and expressed as the corresponding oxides. The results are summarised in Table 1.

**Table 1:** Elemental composition of four batches of the product (expressed as oxide)

	SiO <sub>2</sub> (%)	Al <sub>2</sub> O <sub>3</sub> (%)	Na <sub>2</sub> O (%)	K <sub>2</sub> O (%)	Fe <sub>2</sub> O <sub>3</sub> (%)	MgO (%)	CaO (%)
<b>Mean</b>	38.9	8.9	1.2	5.2	8.4	22.4	4.1
<b>Minimum</b>	38.0	8.5	< 0.05	4.9	7.9	21.9	1.9
<b>Maximum</b>	40.4	9.2	4.1	6.3	8.6	23.9	5.3

##### 3.1.2. Purity

The same batches of vermiculite used to characterise the additive<sup>8</sup> were analysed for heavy metals, arsenic, chromium and nickel content. Lead concentration was in the range of 2–4 mg/kg; mercury, cadmium and arsenic were below the respective limits of quantification (LOQs).<sup>9</sup> Chromium showed an average content of 345 mg/kg (minimum 312–maximum 354 mg/kg), nickel an average content of 236 mg/kg (minimum 204–maximum 310 mg/kg). Fluorine content was analysed in six batches,<sup>10</sup> showing an average content of 1,017 mg/kg (minimum 433–maximum 1,975 mg/kg). These

<sup>7</sup> Technical Dossier/Supplementary Information April 2016/Annex Two (2) Characterization of vermiculite by X-ray Diffraction (XRD).pdf.

<sup>8</sup> Technical Dossier/Supplementary Information April 2016/Annex One (1) Listing Chemical Analysis Reports pertaining to Analysis of Palabora Vermiculite and Annex Three (3) Dupre Appendix 1 PANalytical 2015 dated Chemical Analysis COA from PEL to Dupre.pdf.

<sup>9</sup> Limits of quantification: lead: mercury: 0.6 mg/kg; cadmium: 0.5 mg/kg; arsenic: 1 mg/kg.

<sup>10</sup> Technical Dossier/Supplementary Information April 2016/Annex Three (3) Dupre Appendix 4 Relating to Heavy Metal Fluoride and Arsenic as well as Dioxins and Furans.pdf; Annex Four (4) Summary of Reports related to Dioxin, Furans and PCBs and Annex One (1) Listing Chemical Analysis Reports pertaining to Analysis of Palabora Vermiculite/Scientifics Fluoride Report EJ2018 March 2010\_Palabora (1).pdf.

concentrations comply with the limits set in the Commission Directive 2002/32/EC<sup>11</sup>, where available, and are considered of no concern.

Analysis of dioxins (polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/F) in four batches of the additive<sup>12</sup> resulted in concentrations of 0.07–0.41 ng World Health Organisation (WHO) PCDD/F-TEQ/kg. Dioxin-like PCBs (polychlorinated biphenyls) in three batches were in a range of 0.004–0.029 ng WHO-TEQ/kg. These concentrations comply with the limits set in the Commission Directive 2002/32/EC and are considered of no concern.

### 3.1.3. Physical state of the product

The additive is in an exfoliated form with a bulk density varying between 90 and 120 kg/m<sup>3</sup>.<sup>13</sup> Owing to the large surface area (specified Specific Surface Area: micron grade vermiculite 6.4 m<sup>2</sup>/g, superfine grade vermiculite 5.4 m<sup>2</sup>/g), vermiculite has an elevated absorption capacity. Some examples of the specified absorption capacity are reported for the two-grade vermiculite (micron grade absorption capacity: water 590–610 L/m<sup>3</sup>, paraffin 655–675 L/m<sup>3</sup>; superfine grade absorption capacity: water 510–530 L/m<sup>3</sup>, paraffin 525–545 L/m<sup>3</sup>).

Particle size distribution, analysed in 43 batches of the micron grade vermiculite,<sup>14</sup> showed that > 96% of particles (v/v) were > 100 µm, and < 0.3% of the particles were < 75 µm. The analysis of 38 batches of the superfine grade vermiculite showed that > 97.5% of particles (v/v) were > 100 µm.<sup>15</sup>

Dusting potential was analysed in one batch of the superfine grade vermiculite<sup>16</sup> with the Stauber Heubach method, showing a dusting potential of 705 mg/m<sup>3</sup>. Two batches of the micron grade vermiculite<sup>17</sup> were analysed with the UK MDHS No. 14/3 method,<sup>18</sup> showing dusting potentials of 1.5 and 0.5 mg/m<sup>3</sup>. A last batch of the micron grade vermiculite<sup>19</sup> was analysed with the UK MDHS No. 14/2 method,<sup>20</sup> showing amounts of the respirable fraction of the dust of 8.36 mg/m<sup>3</sup> and of the inhalable fraction of 32.95 mg/m<sup>3</sup>.

No information on interactions and/or incompatibilities of the additive with other feed components was made available.

### 3.1.4. Stability and homogeneity

Stability studies are not required for mineral-based products, which can be reasonably assumed to be stable.

No specific studies on homogenous distribution of the additive in premixture and feedingstuffs were available.

### 3.1.5. Conditions of use

The additive is intended to be used in premixtures and feedingstuffs for pigs, poultry, bovines, sheep, goats, rabbits and horses with no minimum or maximum content. The applicant reported that the maximum inclusion level, deriving from the use of the additive in premixtures of preservatives, is about 50,000 mg/kg complete feed, and suggested typical inclusion levels in complete feedingstuffs below 10,000 mg/kg.

<sup>11</sup> Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels and action thresholds for dioxins and polychlorinated biphenyls. OJ L 140, 30.5.2002, p. 10.

<sup>12</sup> Technical Dossier/Supplementary Information April 2016/Annex Three (3) Dupre Appendix 4 Relating to Heavy Metal Fluoride and Arsenic as well as Dioxins and Furans.pdf and Annex Four (4) Summary of Reports related to Dioxin, Furans and PCBs.

<sup>13</sup> Technical Dossier/Supplementary Information April 2016/Annex 5 Subsection 1 Micron Dupre COAs (1); Annex Five (5) Subsection 2 Superfine Dupre COAs (1).

<sup>14</sup> Technical Dossier/Supplementary Information April 2016/Annex 5 Subsection 1 Micron Dupre COAs (1) and Annex Five (5) Subsection 3 Micron Pull by COAs (2).

<sup>15</sup> Technical Dossier/Supplementary Information April 2016/Annex 5 Subsection 4 Superfine Pull b.v. COAs and Annex Five (5) Subsection 2 Superfine Dupre COAs (1).

<sup>16</sup> Technical Dossier/Supplementary Information April 2016/Annex 5 Isola-Mineralwolle Report No. 3.055 Stauber Heubach test on 1–2 mm Palabora Superfine.pdf.

<sup>17</sup> Technical Dossier/Supplementary Information April 2016/Annex 5 PEL Report 981E Gravimetric Dust sampling and Testing 2003.pdf.

<sup>18</sup> UK Health and Safety Executive (2000). 'General method for sampling and gravimetric analysis of respirable and total inhalable dust' Methods for the Determination of Hazardous Substances No. 14/3. HMSO, London.

<sup>19</sup> Technical Dossier/Supplementary Information April 2016/Annex 5 PEL Crystalline Silica content of 6 vermiculite samples & respirable dust Report 758 24.03.00.pdf.

<sup>20</sup> UK Health and Safety Executive (2000). 'General method for sampling and gravimetric analysis of respirable and total inhalable dust' Methods for the Determination of Hazardous Substances No. 14/2. HMSO, London.

## 3.2. Safety

### 3.2.1. Safety for the target species

The applicant did not provide toxicological studies performed with the additive. Regarding genotoxicity, the applicant only made reference to a statement, not supported by any data, from a mining company: 'In vitro' toxicology studies conducted on aqueous extracts of the product under the auspices of the South African Department of Water Affairs and Forestry in 1998 indicated that the product most probably is not teratogenic or mutagenic. In the studies cited below, a known amount of product was extracted with a litre of distilled water. The resulting extract solution was used to derive the toxicity parameters. The extract was not teratogenic to frog (*Xenopus laevis*) embryos at extract concentrations of 1,000 grams per litre (g/L) and not mutagenic to Salmonella Typhimurium at concentrations of 2,000 g/L. The details of such studies were not provided, and no additional information was made available.

No specific tolerance studies with the target species were provided. Seven publications were instead provided, in which the additive was used for various purposes. Vermiculite was used (i) as a binder for <sup>134</sup>Cs in a study in dairy cows (Hazzard et al., 1969) and for aflatoxin B1 in a study in shrimps (Arunlertaree et al., 2007), (ii) as a carrier, for fats in a study in pigs for fattening (Keaschall et al., 1983) and for vitamin E in two studies in chickens for fattening (Baker et al., 2006 and Lauzon et al., 2008), (iii) as a substitute of roughage in a study in sheep (Dinius et al., 1970) and iv) to restrict the nutrient content of the diet in a study in laying hens (Khokrin and Khan, 1991, available only as an abstract).

None of these studies was designed to fulfil the requirements of a tolerance study. The studies showed a series of limitations which would preclude their use to support the safety of the additive for the target species. The most relevant common limitations were: (i) inadequate study design (e.g. the absence of groups treated with the additive without dietary restrictions or other nutrients, the absence of adequate control groups), (ii) the absence of multiple concentrations of the additive, (iii) very limited set of parameters determined and/or reported (mainly few zootechnical parameters).

Considering the absence of adequate information, the FEEDAP Panel is not in the position to conclude on the safety of the additive for the target species.

### 3.2.2. Safety for the consumer

The FEEDAP Panel considers it unlikely that the additive, in common with other clays, will be degraded during its passage through the gastrointestinal tract of target animals or absorbed to any measurable extent and that harmful amounts of residues of any chemical component would occur in edible tissues/products from animals as a consequence of the use of the product as a feed additive.

Therefore, the use of the additive in animal nutrition is considered not to pose a risk for the consumer of tissues and products from animals fed the additive.

### 3.2.3. Safety for user

The additive is characterised by less than 4% of particles with a diameter below 100 µm. The additive has a low tendency to produce respirable or inhalable dust and does not have crystalline silica. An exposure via inhalation is considered unlikely. However, no specific toxicological studies performed with the additive under assessment were provided. The Panel also notes that the additive showed a nickel content of the additive of 204–310 mg/kg and this could represent a concern for the safety for the user. In the absence of data on the toxicological properties of the additive (including genotoxicity), the Panel is not in the position to conclude on the safety of vermiculite for the user.

### 3.2.4. Safety for the environment

The minerals of the additive are ubiquitous in the environment, being natural components of soil. Therefore, it is not expected that its use as a feed additive would adversely affect the environment.

## 3.3. Efficacy

No specific *in vitro* studies done with the additive were provided to support the efficacy as anticaking or as a binder. The applicant provided two patents (deposited in the USA),<sup>21,22</sup> related to

<sup>21</sup> Technical Dossier/Supplementary Information April 2016/Annex (6) US4034120 (1) Attachment 25.pdf.

<sup>22</sup> Technical Dossier/Supplementary Information April 2016/Annex (6) US20140161864 Attachment 45.pdf.

commercial products containing, among other components, variable amounts of the additive. These reports do not contain full details on the studies used to support the claim and do not allow to evaluate the effect of vermiculite on flowability of feedingstuffs or its effects during pelleting. In addition, the applicant referred to the *in vivo* studies cited under Section 3.2.1. However, these studies do not contain any information useful to assess the efficacy of the additive as anticaking agent or pellet binder.

In the absence of data, the FEEDAP Panel is not in the position to conclude on the efficacy of the additive as anticaking agent and pellet binder in feedingstuffs for all animal species.

#### 4. Conclusions

The FEEDAP Panel could not conclude on the safety of vermiculite for the target species and the users.

The additive is considered safe for the consumers and the environment at the proposed conditions of use.

The FEEDAP Panel could not conclude on the efficacy of vermiculite as a pellet binder and an anticaking agent.

#### 5. Documentation as provided to EFSA/Chronology

Date	Event
22/09/2010	Dossier received by EFSA. Dossier name. Submitted by [name of company]
23/06/2014	Reception mandate from the European Commission
04/03/2015	Application validated by EFSA – Start of the scientific assessment
04/06/2015	Comments received from Member States
04/06/2015	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
08/09/2015	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterization and identification, efficacy</i>
20/04/2016	Reception of supplementary information from the applicant - Scientific assessment re-started
09/06/2016	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: safety for the target species</i>
30/06/2019	Scientific assessment re-started
25/05/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

#### References

- Arunlertaree C, Soonngam L and Hutacharoen R, 2007. Vermiculite and hydrated sodium calcium aluminosilicates as the agent of aflatoxin b1 absorption for black tiger shrimp diets. *Environment and Natural Resources Journal*, 5, 50–58.
- Baker R, Troeschler A, Pelltier W and Pfeiffe A, 2006. Comparing Vitamin E sources for poultry rations. *FEEDMIX*, 14, 14–16.
- Dinius DA, Peterson AD, Long TA and Baumgardt BR, 1970. Intake and digestibility by sheep of rations containing various roughage substitutes. *Journal of Animal Science*, 30, 309–312.
- EFSA (European Food Safety Authority), 2008. Technical Guidance of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) for assessing the safety of feed additives for the environment. *EFSA Journal* 2008;6(10):842, 28 pp. <https://doi.org/10.2903/j.efsa.2008.842>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: tolerance and efficacy studies in target animals. *EFSA Journal* 2011;9(5):2175, 15 pp. <https://doi.org/10.2903/j.efsa.2011.2175>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Guidance for the preparation of dossiers for technological additives. *EFSA Journal* 2012;10(1):2528, 23 pp. <https://doi.org/10.2903/j.efsa.2012.2528>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance on studies concerning the safety of use of the additive for users/workers. *EFSA Journal* 2012;10(1):2539, 5 pp. <https://doi.org/10.2903/j.efsa.2012.2539>
- Hazzard DG, Withrow TJ and Bruckner BH, 1969. Verxite flakes for in vivo binding of cesium-134 in cows. *Journal of Dairy Science*, 52, 995–997.

- Keaschall KE, Moser BD, Peo ER Jr, Lewis AJ and Crenshaw TD, 1983. "Dried fat" for growing-finishing swine. *Journal of Animal Science*, 56, 286–295.
- Khokrin SN and Khan MJ, 1991. Effect of vermiculite on productive performance of white leghorn hens in a controlled feeding system. *Animal Feed Science and Technology*, 35, 301–307.
- Lauzon DA, Johnston SL, Southern LL and Xu Z, 2008. The effect of carrier for vitamin E on liver concentrations of vitamin E and vitamin E excretion in broilers. *Poultry Science*, 87, 934–939.

## Abbreviations

EURL	European Union Reference Laboratory
EFSA	European Food Safety Authority
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
PCBs	polychlorinated biphenyls
PCDD/F	Polychlorinated dibenzo-p-dioxins and dibenzofurans
TEQ	Toxic equivalent
UK MDHS	United Kingdom Methods for the Determination of Hazardous Substances

## **Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for vermiculite**

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  $\text{SiO}_2$  (ca. 35–45%),  $\text{MgO}$  (ca. 20–40%),  $\text{Al}_2\text{O}_3$  (ca. 7–15%) and  $\text{Fe}_2\text{O}_3$  (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.