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**EURL Evaluation Report on the Analytical Methods  
submitted in connection with the Application for the  
Authorisation of Feed Additives according to  
Regulation (EC) No 1831/2003**

Dossier related to: FAD-2010-0233  
CRL/100168

Feed additive: Bentonite (E 558)

Active Substance(s): Bentonite-montmorillonite

Rapporteur Laboratory: European Union Reference Laboratory  
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## EXECUTIVE SUMMARY

In the current application authorisation is sought under articles 4(1) and 10(2) for *Bentonite* under the "technological additives", functional group 2(g) "binders", 2(h) "substances for control of radionuclide contamination" and 2(i) " anti-caking agents", according to the classification system of Annex I of Regulation (EC) No 1831/2003. Authorisation is sought for the use of the *feed additive* for all animal species and categories.

*Bentonite* is a white to beige, green, blue or brown powder or granulates, containing of a minimum of 50 % of dioctahedral smectite (known as montmorillonite). *Bentonite* is intended to be incorporated in *premixtures*, complete or complementary *feedingstuffs*, with no recommended minimum or maximum levels.

For the determination of the mineralogical and geological parameters of the *Bentonite* in the *feed additive*, the Applicant submitted several analytical methods, including X-ray Diffraction (XRD), Methylene-Blue Adsorption, X-Ray Fluorescence (XRF) and Atomic Absorption Spectrometry (AAS). The EURL recommends for official control the X-ray Diffraction (XRD) method for the determination of *Bentonite* in the *feed additive*.

The Applicant did not provide any experimental method or data for the determination of *Bentonite* in *premixtures* and *feedingstuffs*. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Bentonite* in *premixtures* and *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

*Bentonite-montmorillonite*, technological additives, binders, substances for control of radionuclide contamination, anti-caking agents, all animal species and categories.

## 1. BACKGROUND

In the current application authorisation is sought under articles 4(1) (new conditions of use) and 10(2) (re-evaluation of additives already authorised under the provisions of the Council Directive 70/524/EEC) for *Bentonite* under the "technological additives", functional group 2(g) "binders", 2(h) "substances for control of radionuclide contamination" and 2(i) "anti-caking agents" [1], according to the classification system of Annex I of Regulation (EC) No 1831/2003. Authorisation is sought for the use of the *feed additive* for all animal species and categories [2].

*Bentonite* is a white to beige, green, blue or brown powder or granulates, containing of a minimum of 50 % of dioctahedral smectite (known as montmorillonite) [2, 3]. The general formula of *Bentonite* is  $(Ca, Na)(Al, Mg, Fe)_2(Si, Al)_4O_{10}(OH)_2 \cdot nH_2O$  where n represents the variable amount of water [3]. *Bentonite* is intended to be incorporated in *premixtures*, complete or complementary *feedingstuffs*, with no recommended minimum or maximum levels [2]. However, a typical concentration of 25 g/kg *feedingstuffs* is suggested by the Applicant [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 *Bentonite*, 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, mycotoxins, 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 determination of the mineralogical and geological parameters of the *Bentonite* in the *feed additive*, the Applicant proposed several physical (mineralogical) and chemical methods [3], commonly used in geology.

For the physical analysis the Applicant submitted: (i) X-ray Diffraction (XRD) and (ii) Methylene-Blue Adsorption method [3].

- *Bentonite* is identified comparing the XRD pattern to the reference patterns published by the International Centre for Diffraction Database; *Bentonite* is further quantified by means of normalised full pattern reference intensity ratio.
- The Methylene-Blue Adsorption method allows the quantification of the smectite content in *Bentonite* sample by comparison of the methylene blue adsorption of a standard *Bentonite* (with well-known montmorillonite-smectite content). According to the Applicant, Methylene-Blue Adsorption method can be used to quantify the smectite content of a specific bentonite provided that the substance analysed is known to be a bentonite and a well characterised sample of the specific bentonite is used as a standard to compare the adsorption results and calculate the smectite content. However, this method doesn't provide any information about the associated minerals within the bentonite.

For the chemical analysis the Applicant submitted: (i) X-Ray Fluorescence (XRF) and (ii) wet chemical method followed by Atomic Absorption Spectrometry (AAS). The following typical ranges of elemental compositions were provided, depending from the origin of the *Bentonite*: SiO<sub>2</sub> from 51.5 to 72.4 %; Al<sub>2</sub>O<sub>3</sub> from 4.1 to 23.8 %; MgO from 2.4 to 26.1 % and Na<sub>2</sub>O from 1.2 to 3.1 % [3].

The use of all the above mentioned techniques is not necessary in the frame of official control. The EURL recommends for official control the X-ray diffraction (XRD) method proposed by the Applicant for the determination of *Bentonite* in the *feed additive*.

The Applicant is aware that the direct determination of the *Bentonite* content added to *premixtures* or *feedingstuffs* is not achievable by analysis [3], and did not provide any experimental method or data for the determination of *Bentonite* in *premixtures* and *feedingstuffs*. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Bentonite* in *premixtures* and *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**

In the frame of this authorisation the EURL recommends for official control the X-ray Diffraction method submitted by the Applicant for the determination of *Bentonite* in the *feed additive*.

The Applicant did not provide any experimental method or data for the determination of *Bentonite* in *premixtures* and *feedingstuffs*. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Bentonite* in *premixtures* and *feedingstuffs*.

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

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

- X-ray Diffraction (XRD)

#### **5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL**

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Bentonite* 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/D/2 Forw. Appl. 1831/00171 (10187)-2010.
- [2] \* Application, Proposal for Register Entry – Annex A.
- [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.

\* Refers to Dossier No. FAD-2010-0233.

## **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)
- Skúšobné laboratórium – Oddelenie analýzy krmív, Ústredný kontrolný a skúšobný ústav poľnohospodársky, Bratislava (SK)
- Państwowy Instytut Weterynaryjny, Puławy (PL)