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SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of clinoptilolite of sedimentary origin for all animal species[1]

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The additive clinoptilolite of sedimentary origin contains at least 80 % clinoptilolite (hydrated calcium aluminosilicate) and a maximum of 20 % clay minerals. Regarding the limited database and partly controversial findings, the FEEDAP Panel concluded that 10 000 mg clinoptilolite/kg complete feed could be considered to be safe for all animal species. Clinoptilolite is essentially not absorbed and is excreted with the faeces. There is no evidence that clinoptilolite will be degraded during its passage through the gastrointestinal tract of target animals. The consumer is therefore not exposed to clinoptilolite as a result of its use in animal nutrition; consequently, no risk for the consumer will arise. With regard to the high dusting potential of the additive, and in the absence of data on its irritation and sensitisation potential, the FEEDAP Panel considers it prudent to treat the additive as an irritant to the skin and eyes, a dermal sensitiser and an inhalation toxicant. The use of clinoptilolite in animal nutrition does not pose a risk for the environment. Based on data on a large variety of compound feeds, the additive is considered to have the potential to be effective as an anticaking agent. No data were available to allow conclusions to be drawn on its efficacy as a pellet binder. However, as the physical properties required for an anticaking and a pellet-binding additive are similar, and the efficacy of clinoptilolite as an anticaking agent is proven, the FEEDAP Panel considers it likely that the additive also has the potential to be effective as a pellet binder.

KEY WORDS

technological additive, binder, anticaking agent, clinoptilolite of sedimentary origin, safety, efficacy

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[1] On request from the European Commission, Question No EFSA-Q-2012-00582, adopted on 12 December 2012.

[2] Panel members: Gabriele Aquilina, Alex Bach, Vasileios Bampidis, Maria De Lourdes Bastos, Gerhard Flachowsky, Josep Gasa-Gasó, Mikolaj Antoni Gralak, Christer Hogstrand, Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Derek Renshaw, Guido Rychen, Maria Saarela, Kristen Sejrsen, Patrick Van Beelen, Robert John Wallace and Johannes Westendorf. Correspondence: FEEDAP@efsa.europa.eu

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SUMMARY

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 the safety and efficacy of clinoptilolite of sedimentary origin as a technological additive, functional group binder.

The additive clinoptilolite of sedimentary origin contains at least 80 % clinoptilolite (hydrated calcium aluminosilicate) and a maximum of 20 % clay minerals.

Regarding the limited database and partly controversial findings, the FEEDAP Panel concluded that 10 000 mg clinoptilolite/kg complete feed could be considered to be safe for all animal species.

Clinoptilolite is essentially not absorbed and is excreted with the faeces. There is no evidence that clinoptilolite will be degraded during its passage through the gastrointestinal tract of target animals. The consumer is therefore not exposed to clinoptilolite as a result of its use in animal nutrition; consequently, no risk for the consumer will arise.

With regard to the high dusting potential of the additive, and in the absence of data on its irritation and sensitisation potential, the FEEDAP Panel considers it prudent to treat the additive as an irritant to the skin and eyes, a dermal sensitiser and an inhalation toxicant.

The use of clinoptilolite in animal nutrition does not pose a risk for the environment.

Based on data on a large variety of compound feeds, the additive is considered to have the potential to be effective as an anticaking agent. No data were available to allow conclusions to be drawn on its efficacy as a pellet binder. However, as the physical properties of an anticaking and a pellet-binding additive must be similar in binding small particles by adsorption, the FEEDAP Panel considers it likely that the additive also has the potential to be efficacious as a pellet binder.

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BACKGROUND

Regulation (EC) No 1831/2003[4] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7, and 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 Unipoint AG[5] for authorisation/re-evaluation of the product clinoptilolite of sedimentary origin, when used as a feed additive for all animal species (category: technological additive; functional group: binders) under the conditions mentioned in Table 1.

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 4(1) (authorisation of a feed additive or new use of a feed additive) and 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.[6] According to Article 8 of that Regulation, 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. The particulars and documents in support of the application were considered valid by EFSA as of 25 June 2012.[7]

Clinoptilolite of sedimentary origin is currently authorised as feed additive for use as a technological additive (functional group (g, i), binders, anti-caking agents) in feedingstuffs for pigs for fattening, chickens for fattening, turkeys for fattening, bovine and salmon with a maximum concentration of 20000 mg/kg complete feedingstuffs.

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall 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 the efficacy of the product clinoptilolite of sedimentary origin, when used under the conditions described in Table 1.

[4] 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.
[5] Unipoint AG, Gewerbestrasse 2, 8475, Ossingen, Switzerland (represented in the EU by Heforma GmbH, August-Wegmann_strasse 65, 4452 Lunen, Germany.
[6] EFSA Dossier reference: FAD-2009-0017.
[7] A new mandate was received by EFSA on 8 May 2012.

Table 1: Description and conditions of use of the additive as proposed by the applicant

Additive	**Binder**
Registration number/EC No/No (if appropriate)	**E 568**
Category(-ies) of additive	**Technological additive**
Functional group(s) of additive	**Binder**

Description			
Composition, description	Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)
Clinoptilolite of sedimentary origin	**SiO Silicate**	**80 % clinoptiloite 20 % clay**	**x-ray RDF**

Trade name (if appropriate)	
Name of the holder of authorisation (if appropriate)	Unipoint AG Gewerbestrasse 2 CH-8475 Ossingen info@unipoint.ch

Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period (if appropriate)
		mg/kg of complete feedingstuffs		
all animals	----	----	**20,000 mg/kg**	----

Other provisions and additional requirements for the labelling	
Specific conditions or restrictions for use (if appropriate)	none
Specific conditions or restrictions for handling (if appropriate)	none
Post-market monitoring (if appropriate)	none
Specific conditions for use in complementary feedingstuffs (if appropriate)	none

Maximum Residue Limit (MRL) (if appropriate)			
Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues
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ASSESSMENT

This opinion is based in part on data provided by a single company involved in the production/distribution of the active substance. It should be recognised that this data covers only a fraction of the existing additives containing the active substance. The FEEDAP Panel has sought to use the data provided together with data from other sources to deliver an opinion.

1. Introduction

Clinoptilolite of sedimentary origin (hydrated calcium aluminosilicate of sedimentary origin containing at least 80 % clinoptilolite and a maximum 20 % of clay minerals, free of fibres and quartz) is currently listed in the European Union Register of Feed Additives[8] as a technological additive (functional groups (g, i), binders, anticaking agents) in feedingstuffs for pigs for fattening, chickens for fattening, turkeys for fattening, bovines and salmonids with a maximum concentration of 20 000 mg/kg complete feedingstuff. The applicant is seeking the re-evaluation of clinoptilolite of sedimentary origin as a technological additive and its authorisation for all animal species.

Clinoptilolite of sedimentary origin has been assessed by the Expert Group for Technical Advice on Organic Food (EC, 2011).

2. Characterisation

Clinoptilolite is a natural zeolite comprising a microporous arrangement of silica and alumina tetrahedra. It was described in 1969 from an occurrence in Owl Canyon, California. The name is derived from the Greek words *klino* (oblique), *ptylon* (feather) and *lithos* (stone).

Clinoptilolite of sedimentary origin is a finely ground stonemeal of natural aluminium silicate. Clinoptilolite of sedimentary origin can bind water molecules in the zeolite pores. Besides the tightly and loosely bound zeolitic water there is also external water, which escapes at temperatures as low as 30° C in a vacuum. Through contact between the zeolite and ions in an aqueous solution the ions can be adsorbed. The specific surface of the zeolite (its size, geometry and energetic characteristics) also influences the ion adsorption (EC, 2011).

2.1. Characterisation of the active substance

The raw material is excavated by mining. The resulting blocks are broken. The material is heated at 300° C for at least one hour. The subsequent milling process is adjusted to guarantee a constant particle size.

Natural clinoptilolites are characterised primarily by the content of clinoptilolite and secondly by the presence of clays. X-ray diffraction (XRD) is commonly used to provide a full mineralogical analysis. The additive clinoptilolite of sedimentary origin has by specification a minimum clinoptilolite content of 80 % and a maximum clay content of 20 %. Data from the XRD analysis of six batches revealed an average of 92 % clinoptilolite (range 88–95 %) in the additive.[9] Comparing the diffractograms of the six samples with a standard clinoptilolite source (Hector clinoptilolite standard) revealed a high degree of similarity, confirming the identity of the additive. The main chemical composition of clinoptilolite over eight batches was about 67 % SiO_2, 12 % Al_2O_3, 3 % CaO, 1.3 % Fe_2O_3, and 0.7 %Na_2O.[10]

[8] European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003. Available from: http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf

[9] Supplementary information June 2010/Annex 1 and Annex 2; Technical dossier/Supplementary information December 2010/Annex 1.

[10] Supplementary information June 2010/Annex 6, Annex 7 and Annex 8; Technical dossier/Supplementary information December 2010/Annex 2.

Three samples of clinoptilolite of sedimentary origin showed concentrations of heavy metals: Cd < 0.04, Pb < 7.4, Hg < 0.005 and As < 1.4 mg/kg.[11] Dioxins in four batches analysed did not exceed 0.1 ng WHO-PCDD/F-PCB-TEQ/kg,[12] in compliance with the Directive 2002/32/EC[13]

Data from laser diffraction analysis of one batch of the additive identified 90 % (v/v) of the particles with a diameter ≤ 186 µm, 50 % with a diameter ≤ 72 µm and 31 % with a diameter ≤ 50 µm.[14] Laser diffraction analysis of three other batches identified 50 % of the particles falling within the respirable fraction (≤ 8 µm) and 10 % of the particles ≤ 1 µm .[15]

The dusting potential of the additive, measured over seven batches according to the Stauber–Heubach method, was about 1.53 g/m^3 air.[16] The dust fraction consisted of 90 % of particles with a diameter of ≤ 23 µm, 50 % with a diameter of ≤ 4 µm and 10 % with a diameter of ≤ 0.6 µm.[17]

2.2. Stability and homogeneity

No data were provided on the shelf-life of the additive or on the stability of the additive in feedingstuffs and premixtures. Stability studies are not normally required for mineral-based products. Similar considerations can be applied to clinoptilolite of sedimentary origin.

Homogeneity studies are not considered necessary for a binder and an anticaking additive as long as their efficacy can be demonstrated.

2.3. Conditions of use

The additive is intended to be used in the processing of compound feedingstuffs as a binder and an anticaking agent. The applicant proposes to maintain the current authorised maximum content of 20 000 mg/kg complete feed for all animal species. However, the applicant also suggests a recommended level of use between 2 000 and 10 000 mg/kg feed.

2.4. Evaluation of the analytical methods by the European Union Reference Laboratory (EURL)

EFSA has verified the EURL report as it relates to the methods used for the control of clinoptilolite of sedimentary origin in animal feed. the executive summary of the EURL report can be found in the Appendix.

3. Safety

3.1. Safety for the target species

No specific tolerance studies were provided. Upon the request of the FEEDAP Panel, the applicant performed a structured database search using diverse scientific databases to provide information on target animal safety and interactions with other feed components.[18] Radiographic analysis showed that the pores of clinoptilolite of sedimentary origin have a diameter of 4 Å, which limits trapping to ions of smaller diameter. Adsorption decreases in the order $Cs^+ > NH_4^+ > Cu^{2+} >$

[11] Supplementary information June 2010/Annex 9, Annex 10 and Annex 11.
[12] Technical dossier/Section III/Annex_III_4.
[13] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).
[14] Supplementary information June 20120/Section II/Annex 12.
[15] Supplementary information March 2011/E 568 Klinofeed Test Report No. 2.419_2 PSD.
[16] Technical dossier/section III/Annex III.3, Technical dossier/Supplementary information June 20120/Section II/Annex 13 and Technical dossier/Supplementary information December 2010/Annex 3.
[17] Supplementary information March 2011/E 568 Klinofeed Test Report No. 2.419_2 PSD.
[18] Supplementary information December 2010/Annex 4.

$Zn^{2+} > Sr^{2+} > Cd^{2+} > Ni^{2+} > Co^{2+}$.[19] Major effects of dietary clinoptilolite on the mineral status of growing and finishing pigs and growing lambs were not found (Pond, 1984); however, some changes in the mineral concentration of the kidney of pigs were found (Pond, 1988). Papaioannou et al. (2002) studied the effect of 2 % clinoptilolite in sow feed on serum and tissue concentrations of vitamin A and E and the mineral elements K, Na, P, Ca, Mg, Cu and Zn. The authors did not find any relevant effects that could be attributed to clinoptilolite. However, controversial findings can be found in the literature. Martin-Klainer et al. (2001) described a 20 % increase in serum potassium in mice after administration of clinoptilolite-supplemented diets while Gerasev et al. (2003a) described reduced potassium absorption and increased renal excretion in rats (Gerasev et al., 2003b). Alterations in the mineral concentration in blood or tissues of different species (pigs: Pond et al. 1988; chicken: Scheideler, 1993) are balanced by findings of a beneficial growth response in pigs (Cool and Willard, 1982; Coffey and Pilkington, 1989; Yannakopoulos et al, 2000). Alexopoulos et al. (2007) studied the effect of clinoptilolite in 48 growing pigs (trial duration 136 days) on biochemical and haematological parameters; the authors concluded that the long-term dietary use of clinoptilolite at an inclusion rate of 2 % appeared to enhance the performance of growing and fattening pigs without adversely affecting their health status in terms of undesirable changes in their biochemical and haematological profiles. Poulsen and Oksbjerg (1994) fed diets containing 0 and 3 % clinoptilolite to growing pigs. The inclusion of clinoptilolite tended to decrease daily gain and to increase feed to gain ratio. Karatzia et al. (2011) administered 200 g clinoptilolite per head per day (corresponding to approximately 15 000 mg clinoptilolite/kg feed dry matter) to a group of eight rumen-fistulated Holstein cows, another eight cows remaining untreated. During the observation period of 12 weeks, clinoptilolite feeding resulted in an increase in ruminal pH and acetate in the ruminal fluid and a decrease in propionate.

3.1.1. Conclusions on safety for the target species

No typical tolerance studies were provided or found in the literature. In the studies reported the most frequently used concentration of clinoptilolite in feed was approximately 20 000 mg/kg, which corresponds to the currently authorised maximum content. Furthermore, the endpoints required to assess safety for the target animals were not consistently reported. Considering the adverse, albeit unclear, effect on the mineral status of pigs, chickens and dairy cows and the effects of approximately 15 000 mg clinoptilolite/kg on rumen fermentation it seems prudent not to consider 20 000 mg clinoptilolite/kg in complete feed as safe for all animal species. However, the range proposed by the applicant, 2 000–10 000 mg clinoptilolite/kg complete feed, appears to be safe for all animal species.

3.2. Safety for the consumer

Clinoptilolite has a stable crystal structure, with mineral-specific ion exchange and adsorption properties and reversible hydration capacity. Clinoptilolite is essentially not absorbed and is excreted with the faeces. There is no evidence that clinoptilolite will be degraded during its passage through the gastrointestinal tract of the target animals.

The consumer is therefore not exposed to clinoptilolite as a result of its use in animal nutrition; consequently, no risk for the consumer will arise.

3.3. Safety for the user

In view of the absence of quartz and fibres (potential causes of lung toxicity) in clinoptilolite, no specific inhalation toxicity study was provided by the applicant,. However, the additive has a high dusting potential. The applicant performed a structured database search using diverse scientific databases to provide information on the effects of clinoptilolite (and silicates) on the lungs, skin and eyes.[20] No information specific for clinoptilolite of sedimentary origin were found in the literature. In the absence of any data on its irritation and sensitisation potential, the FEEDAP Panel considers it

[19] Supplementary information December 2010/Annex 4.
[20] Technical dossier/Supplementary information December 2010/Annex 4.

prudent to treat the additive as an irritant to the skin and eyes, a dermal sensitiser and an inhalation toxicant.

3.4. Safety for the environment

Clinoptilolite is a naturally occurring mineral, it is excreted unchanged and does not decompose in slurries, farmyard manure and litter. The use of clinoptilolite of sedimentary origin in animal nutrition will not increase its concentration in the environment.

Consequently, the use of clinoptilolite in animal nutrition does not pose a risk for the environment.

4. Efficacy

4.1. Anticaking activity

The efficacy of an additive as an anticaking agent can be demonstrated by measuring the flowability of feed materials or compound feed, without and with the additive. A standard procedure, described by Jenike (1967), allows assessment of the flowability and the anticaking properties of the material. The outcome is expressed as a factor (ffc) which identifies improved flowability by increasing values. Jenike (1967) suggested the classification described in Table 2.

Table 2: Classification of the flow properties of the feed materials according to Jenike (1967)

ffc	Flow properties of the feed materials
< 2	Very cohesive, not flowing
> 2 and < 4	Cohesive
> 4 and < 10	Slightly flowing
> 10	Free flowing

ffc, flow factor according to Jenike (1967).

Flowability is influenced, among others things, by the particle size of the feed material (coarse particles showing better flowability than smaller particles) and by solidification (i.e., by compaction). The applicant submitted three studies on the influence of clinoptilolite on the flowability of different feed formulations. The results are summarised in Table 3.

Table 3: Effect of clinoptilolite on the flowability of different feedingstuffs with or without storage time (allowing compaction)

Type of feed	Feed particle size[a] X_{50}, mm	Clinoptilolite (%)	Storage time (Solidification)[b]	ffc
Piglet feed	0.39	0	–	6.4
		1	–	9.7
		2	–	11.5
		0	+	2.2
		1	+	2.9
		2	+	2.8
Piglet feed	0.46	0	–	4.5
		2	–	4.8
		0	+	1.9
		2	+	2.6
Sow feed	0.70	0	–	14.0
		2	–	10.7
		0	+	1.7
		2	+	2.1
Cattle feed	0.58	0	–	36.7
		1	–	14.5
		2	–	50.9
		0	+	2.1
		1	+	2.2
		2	+	2.4
Layer feed	1.34	0	–	13.0
		2	–	26.8
		0	+	2.3
		2	+	4.0
Dog feed	0.23	0	–	3.0
		2	–	4.0
Cat feed	0.19	0	–	4.2
		2	–	5.1
		0	+	2.5
		2	+	2.8
Rabbit feed	0.48	0	–	13
		2	–	11
		0	+	2.5
		2	+	3.4
Horse feed	0.51	0	–	12
		2	–	8.5
		0	+	3.2
		2	+	3.4

ffc, flow factor according to Jenike (1967).
a Expressed as the median diameter of 50 % of the particles.
b Storage time of one day in a translation shear cell with 1.5 kg load at ambient conditions (18 °C; 60 % relative humidity).

In compound feed with cohesive proprieties (e.g., smaller particle size and/or after solidification) clinoptilolite has the potential to improve the flowability. The effect tends to disappear in feedingstuffs that are already free flowing without the addition of an anticaking agent.

4.2. Pellet binder

The binding efficacy of an additive can be measured by determining hardness and durability of pellets. Durability is mostly determined after treatment of a pellet sample in a tumbler canister. The amount of fine particles (< 2.83 mm) released is measured and expressed as a percentage of the intact pellet sample (pellet durability index, PDI). The applicant submitted a statement on the PDI of a duck feed

pelleted with 0.3 % clinoptilolite, which was compared with other potential binders (guar gum and gelatine), but not with untreated feed. The PDI for the clinoptilolite-treated feed was 97.2, for guar gum and gelatine 97.4 and 97.8, respectively.

The data provided do not allow conclusions to be drawn on the efficacy of clinoptilolite as pellet binder. However, as the physical properties of an anticaking and a pellet binding additive must be similar in binding smaller particles, and the efficacy of clinoptilolite as an anticaking agent is proven, it is considered likely that the additive would also be effective as a pellet binder.

4.3. Conclusions on efficacy

Based on data on a large variety of compound feeds, the additive is considered to have the potential to be effective as an anticaking agent. No data were available to conclude on its efficacy as a pellet binder. However, as the physical properties of an anticaking and a pellet binding additive must be similar in binding small particles by adsorption, the FEEDAP Panel considers it likely that the additive also has the potential to be efficacious as a pellet binder.

CONCLUSIONS

Regarding the limited database and partly controversial findings, the FEEDAP Panel concluded that 10 000 mg clinoptilolite/kg complete feed could be considered safe for all animal species.

Clinoptilolite is essentially not absorbed and is excreted with the faeces. There is no evidence that clinoptilolite will be degraded during its passage through the gastrointestinal tract of target animals. The consumer is therefore not exposed to clinoptilolite as a result of its use in animal nutrition; consequently, no risk for the consumer will arise.

With regard to the high dusting potential of the additive, and in the absence of data on its irritation and sensitisation potential, the FEEDAP Panel considers it prudent to treat the additive as an irritant to the skin and eyes, a dermal sensitiser and an inhalation toxicant.

The use of clinoptilolite in animal nutrition does not pose a risk for the environment.

Based on data on a large variety of compound feeds the additive is considered to have the potential to be effective as an anticaking agent. No data were available to allow conclusions to be drawn on its efficacy as a pellet binder. However, as the physical properties of an anticaking and a pellet binding additive must be similar in binding small particles by adsorption, the FEEDAP Panel considers it likely that the additive also has the potential to be efficacious as a pellet binder.

DOCUMENTATION PROVIDED TO EFSA

1. Clinoptilolite of sedimentary origin for all animal species. May 2009. Submitted by Unipoint AG.

2. Clinoptilolite of sedimentary origin for all animal species. Supplementary information. June 2010. Submitted by Unipoint AG.

3. Clinoptilolite of sedimentary origin for all animal species. Supplementary information. December 2010. Submitted by Unipoint AG.

4. Clinoptilolite of sedimentary origin for all animal species. Supplementary information. March 2011. Submitted by Unipoint AG.

5. Evaluation report of the European Union Reference Laboratory for Feed Additives on the methods(s) of analysis for clinoptilolite of sedimentary origin.

6. Comments from Member States received through the ScienceNet.

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APPENDIX

Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the method(s) of analysis for clinoptilolite of sedimentary origin[21]

In the current application authorisation is sought for clinoptilolite under article 4(1) and article 10(2), under the category "technological additives", functional group (1f) "binders" according to Annex I of Regulation (EC) No 1831/2003. Specifically, authorisation is sought for the feed additive to be placed on the market in the form of powder containing a minimum of 80 % clinoptilolite and a maximum of 20 % clay. The intended use of the current application is for all animal species. The additive can be used in pelleted mixed feeds and in feeds in the form of meal at a maximum content of 20 g/kg.

For the determination of clinoptilolite in the feed additive the applicant proposes the X-ray diffraction method. The sample diffractograms are compared with the standard pattern of the Hector material, containing 90 % clinoptilolite. The CRL recommends for official control the method submitted by the applicant for the determination of clinoptilolite in the feed additive.

The unambiguous determination of the clinoptilolite content added to premixtures or feedingstuffs is not achievable by analysis. The applicant did not provide any experimental method or data on this matter. Furthermore, no international standard methods of analysis could be identified. Therefore the CRL cannot evaluate or recommend any method for official control to determine clinoptilolite in premixtures or 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.

[21] The full report is available on the EURL website: http://irmm.jrc.ec.europa.eu/SiteCollectionDocuments/FinRep-FAD-2009-0017.pdf