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SCIENTIFIC OPINION

Safety and efficacy of the feed additive consisting of clinoptilolite of sedimentary origin for all animal species for the renewal of its authorisation (ZEOCEM, a.s.)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | **Roberto Edoardo Villa** | **Giovanna Azimonti** | **Eleftherios Bonos** | **Henrik Christensen** | **Mojca Durjava** | **Birgit Dusemund** | **Ronette Gehring** | **Boet Glandorf** | **Maryline Kouba** | **Marta López-Alonso** | **Francesca Marcon** | **Carlo Nebbia** | **Alena Pechová** | **Miguel Prieto-Maradona** | **Ilen Röhe** | **Katerina Theodoridou** | **Jaume Galobart** | **Orsolya Holczknecht** | **Fabiola Pizzo** | **Anita Radovnikovic** | **Maria Vittoria Vettori** | **Angelica Amaduzzi**

Correspondence: feedap@efsa.europa.eu

The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

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 the assessment of the application for renewal of authorisation of clinoptilolite of sedimentary origin as a technological feed additive (binder and anticaking agents) for all animal species. The applicant provided evidence that the additive currently on the market complies with the existing conditions of authorisation. The Panel concludes that clinoptilolite of sedimentary origin remains safe for all animal species, consumers and the environment under the authorised conditions of use. Regarding user safety, the additive is not a skin nor an eye irritant but should be considered a skin and respiratory sensitiser. Inhalation and dermal exposure are considered a risk. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

KEYWORDS

anticaking agents, binders, clinoptilolite, efficacy, renewal, safety, technological additive

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest 1 year before the expiry date of the authorisation.

The European Commission received a request from ZEOCEM a.s.[2] for the renewal of the authorisation of the additive consisting of clinoptilolite of sedimentary origin, when used as a feed additive for all animal species (category: technological additives; functional groups: binder and 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 14(1) (renewal of the authorisation). 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 10 January 2023.

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 feed additive consisting of clinoptilolite of sedimentary origin, when used under the proposed conditions of use (see **Section 3.1.2**).

1.2 | Additional information

The additive clinoptilolite of sedimentary origin is currently authorised for use in feed for all animal species (1g568).[3] EFSA issued an opinion on the safety and efficacy of this product when used in feed for all animal species (EFSA FEEDAP Panel, 2013).

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[4] in support of the authorisation request for the use of clinoptilolite of sedimentary origin as a feed additive. The dossier was received on 26/7/2022 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00474.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 11 January 2023 to 10 April 2023 for which received comments that were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[6] a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[7] EFSA carried out a public consultation on the non-confidential version of the technical dossier from 24 October to 14 November 2023 for which no comments were received.

In addition, the confidential version of the technical dossier was subject to a target consultation of the interested Member States from 10 January 2023 to 10 April 2023 for which received comments that were considered for the assessment.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the clinoptilolite of sedimentary origin in animal feed are valid and applicable for the current application.[8]

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

[2]ZEOCEM, a.s.; Bystré 282, SR, 09434, Bystré, Slovakia.

[3]Commission Implementing Regulation (EU) No 651/2013 of 9 July 2013 in OJ L 189, 10.07.2013, p. 1.

[4]Dossier reference: FEED-2022-3133.

[5]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, pp. 1–48.

[6]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[7]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[8]Evaluation report received on 14/7/2010 and available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of clinoptilolite of sedimentary origin is in line with the principles laid down in Regulation (EC) No 429/2008[9] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3 | ASSESSMENT

Clinoptilolite of sedimentary origin is currently authorised as a technological additive (functional groups: binders and anti-caking agents) for use in feed for all animal species. This assessment regards the renewal of this authorisation.

3.1 | Characterisation

3.1.1 | Characterisation of the active substance/additive

The additive named clinoptilolite of sedimentary origin is a powder which contains as active substances at least 80% clinoptilolite (hydrated calcium aluminosilicate) of sedimentary origin and a maximum of 20% of clay minerals (free of fibres and quartz). The Chemical Abstracts Service (CAS) number of clinoptilolite is 12173-10-3 and the EC number is 687-562-6.

The applicant states that no modifications to the manufacturing process or composition of the additive have been introduced since the original authorisation.[10]

The applicants provided analytical data on the mineralogical composition performed by X-ray diffraction (XRD),[11] elemental analysis by inductively coupled plasma–atomic emission spectrometry (AES–ICP)[12] and impurities[13] (see Table 1).

TABLE 1 Specifications for the additive clinoptilolite of sedimentary origin, and analytical data on the batch-to-batch variation, impurities and physical properties.

		Analysis		
Parameter	**Specification**	**Average**	**Range**	**# Batches**
Mineralogical analysis (XRD)				
Clinoptilolite (%)[a]	≥ 80%	84.4	82–≥ 90	10
Clay minerals (%)[a]	≤ 20%	≤ 5	≤ 5	5
Fibre and quartz	Free	–	–	5
Elemental analysis (AES–ICP)[b]				
SiO_2 (%)		69.8	69.2–70.3	5
Al_2O_3 (%)		12.2	12–12.5	5
CaO (%)		3.2	3.1–3.2	5
K_2O (%)		3.2	3.1–3.2	5
Fe_2O_3 (%)		1.7	1.7–1.8	5
Na_2O (%)		1.2	1.2–1.3	5
MgO (%)		0.6	0.5–0.7	5
TiO_2 (%)		0.2	0.2	5
Moisture		3.9	3.9	5
Loss on ignition		7.5	7.5	5
Impurities (mg/kg)				
Lead			9.99–11.05	3
Mercury			0.008–0.010	3
Cadmium			0.027–0.033	3
Arsenic			1.27–1.48	3

[9]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. 1.

[10]Technical dossier/ 3.1_Safety_for_target_animals.

[11]Technical dossier/ Annex II.1.2 and Annex_01_AddInfo_03_2025_Min_ana_Confidential.pdf.

[12]Technical dossier/ Annex II.1.3.

[13]Technical dossier/ Annex II.1.4, Annex II.1.5, Annex II.1.6, Annex II.1.8.

TABLE 1 (Continued)

Parameter	Specification	Analysis		
		Average	Range	# Batches
Nickel			0.6–1.8	5
Fluorine			< 8.8	3
Dioxins and furans (upper bound)[c]				
PCDD/Fs (ng WHO_{2005}-TEQ/kg)				3
PCDD/Fs + DL-PCBs (ng WHO_{2005}-TEQ/kg)				3
non DL-PCBs (µg/kg)			0.40–0.43	3
Physical properties				
Dusting potential (Stauber Heubach) (mg/m^3)			4035–4305	3
Particle size distribution of the additive (laser diffraction) (% of particles below, v/v)				3
100 µm			10.7–13	
50 µm			8.6–10.2	
10 µm			5.5–6.6	
1 µm			0.9–1.1	
Particle size distribution of the dust (laser diffraction) (% of particles below, v/v)				3
50 µm			90.9–91.7	
10 µm			73.4–75.3	
5 µm			41.5–42.8	
1 µm			10.2–10	

Note: <: below the reporting limit.

Abbreviations: AES–ICP, inductively coupled plasma–atomic emission spectrometry; nDL-PCBs, non-dioxin-like PCBs; PCBs, polychlorinated biphenyls; PCDDs, polychlorinated dibenzo-*p*-dioxins; PCDFs, polychlorinated dibenzofurans; TEQ, toxic equivalent factors for dioxins, furans and dioxin-like PCBs established by WHO in 2005 (Van den Berg et al., 2006); WHO, World Health Organization; XRD, X-ray diffraction.

[a]Specifications set in Regulation (EU) No 651/2013.

[b]Expressed as oxides.

[c]Upper bound (UB) concentrations calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification. TEQ = toxic equivalency factors for dioxins, furans and dioxin-like PCBs established by WHO in 2005 (van den Berg et al., 2006).

The data provided by the applicant showed compliance with the specifications set in the authorising regulation for the additive clinoptilolite of sedimentary origin. The FEEDAP Panel considers that the detected amounts of the above-described impurities do not raise safety concerns, except nickel, the safety of which is addressed in Section 3.2.1.

Since no changes were introduced in the additive manufacturing process, the data described in the previous opinion with regards to the physico-chemical and technological properties still apply (EFSA FEEDAP Panel, 2013). Additional data were provided on the dusting potential and particle size distribution (see Table 1).

The presence of small/nanoparticles was investigated using transmission electron microscopy (TEM) following the criteria of the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021).[14] The data confirmed that the additive under assessment contains a fraction of particles at the nanoscale by showing that more than 10% particles (number-based) have at least one dimension smaller than 500 nm (85%, 83% and 85% for three replicate analyses) while 67%, 69% and 71% of particles (total) are < 250 nm. Following a recalculation, this resulted in 78%, 65% and 84% of the particles < 250 nm of the fraction < 500 nm.

3.1.2 | Conditions of use

The additive is currently authorised to be used as binder and anticaking agent in feed for all animal species with a maximum level of 10,000 mg/kg complete feed. Under other provisions of the authorisations, it is specified that:

- For safety: it is recommended to use breathing and eyes protections and gloves during handling.
- Total quantity of clinoptilolite of sedimentary origin from all sources shall not exceed the maximum content of 10,000 mg.

[14]Technical dossier/ Annex II.1.10.

The applicant did not request any change in the current conditions of the authorisation.

3.2 | Safety

In its previous opinion (EFSA FEEDAP Panel, 2013), the FEEDAP Panel concluded that the additive clinoptilolite of sedimentary origin is safe up to 10,000 mg/kg for the target species, the consumer and the environment. With regards to user safety, the Panel considered, in the absence of data, that it should be treated as an irritant to the skin and eyes, a dermal sensitiser and an inhalation toxicant.

The applicant states that no incidents or safety issues have been documented or reported since the previous authorisation.[15]

The applicant performed an extensive literature search (ELS) to support that the additive remains safe for target species, consumers, users and the environment, under the approved conditions (see Section 3.2.2). In addition, new data on the genotoxicity and on the safety for the user were submitted (see Sections 3.2.1 and 3.2.4).

3.2.1 | Genotoxicity studies

The studies were conducted with a test item called 'natural zeolite' which was confirmed to be the additive under assessment.[16]

3.2.1.1 | *Bacterial reverse mutation test*

In order to investigate the potential of the additive clinoptilolite of sedimentary origin to induce gene mutations in bacteria, an Ames test was performed according to the OECD TG 471 (1997) and following GLP principles in Salmonella Typhimurium strains TA97a, TA98, TA100, TA102 and TA1535.[17] Two independent experiments were performed applying the plate incorporation method both in the presence and absence of metabolic activation. The additive was suspended in deionised water and tested at concentrations of 62, 185, 556, 1667 and 5000 μg per plate, both with and without an external metabolising system (S9-mix from Aroclor 1254 induced rats). No toxicity was observed up to 5000 μg per plate. A slight precipitate was visible at higher concentrations but did not impede the evaluation. No increase in mutation frequency was observed in any of the tested concentrations or strains, with or without metabolic activation. Appropriate positive and negative controls were evaluated concurrently, and all positive control chemicals induced significant increases in the number of revertant colonies, confirming the sensitivity of the test system and efficacy of the metabolic activation system. Therefore, the FEEDAP Panel concludes that the soluble part of the test item, if any, does not induce gene mutations under the experimental conditions employed in the study.

3.2.1.2 | In vitro *mammalian micronucleus test*

To evaluate the potential of the additive clinoptilolite of sedimentary origin to induce chromosome damage, an in vitro micronucleus test was carried out using a human lymphoblastoid cell line (TK6) according to OECD TG 487 (2023) and following GLP principles.[18] The TK6 cells were treated with the additive suspended in water or control substances under three experimental conditions: short-term treatment for 3 h in the absence of S9 mix followed by a 24-h recovery period in the presence of cytochalasin B (-S9 assay); short-term treatment for 3 h in the presence of S9 mix followed by a 24-h recovery period in the presence of cytochalasin B (+S9 assay); and continuous treatment for 24 h in the absence of S9 mix but in the presence of cytochalasin B (24 h assay). Based on the results of the cell growth inhibition test, the test was conducted at concentrations of 15.6, 31.3, 62.5 and 125 μg/mL. Micronucleus analysis was conducted at 31.3, 62.5 and 125 μg/mL for the -S9, +S9 and 24 h assays. Precipitation of the test substance was observed at 125 μg/mL in all assays. No inhibition of cell growth was observed at any of the tested concentrations. Positive control chemicals induced statistically significant increases in the frequency of micronucleated binucleate cells (MNBN), confirming the sensitivity of the assay and efficacy of the metabolic activation system. No statistically significant increases in the frequencies of MNBN were observed in any of the groups treated with the test substance compared to the negative control group. The frequencies were within the acceptable ranges calculated from the historical negative control data. Therefore, the FEEDAP Panel concludes that the soluble part of the test item did not induce micronuclei in cultured mammalian cells under the experimental conditions applied in this study.

[15]Technical dossier/ Annex III.3.2.

[16]Technical dossier/ 2024 09 17 Reply EFSA RFI 19.03.2024 and 2024 03 08 Reply EFSA RFI 29.2.2024.

[17]Technical dossier/ Annex_SIn_IV_01.

[18]Technical dossier/ Annex_SIn_IV_02.

3.2.1.3 | *Conclusions on genotoxicity*

Based on the results of the available studies, the FEEDAP Panel concludes that the additive under assessment shows no genotoxic potential under the tested conditions.

3.2.2 | Extensive literature search

The applicant performed an ELS to support that the additive remains safe under the approved conditions for the target animals, consumers, users and the environment.[19] The search covered the period 2010–2022, the language of the search was restricted to English. The following databases were used: Cab Abstracts PubMed (in NCBI webpage). The search protocol described the inclusion and exclusion criteria applied for the screening process. In total 412 articles were considered for the screening and after applying the inclusion/exclusion criteria, a total of 59 scientific papers were considered eligible by the applicant for the safety for the target species. The FEEDAP Panel reviewed all the relevant papers and considered that none of them contained any new information that would lead the Panel to reconsider its previous conclusions.

3.2.3 | Safety for the target species, consumers and the environment

Considering the outcome of the ELS, the genotoxicity studies and the fact that the manufacturing of the additive, specifications and conditions of use have not been modified, the FEEDAP Panel concludes that the additive, clinoptilolite of sedimentary origin, remains safe for the target species, consumers and the environment under the current conditions of authorisation.

3.2.4 | Safety for the user

In the previous opinion, the FEEDAP Panel concluded that, in the absence of data, the additive should be considered as irritant to skin and eyes, a dermal sensitiser and an inhalation toxicant (EFSA FEEDAP Panel, 2013).

Based on the highest dusting potential measured (4305 mg/m^3), the FEEDAP Panel considers that the exposure of users through inhalation is likely.

The FEEDAP Panel notes that the additive contains nickel (0.6–1.8 mg/kg). The Directive (EU) No 2022/431 set an occupational exposure limit (OEL) of 0.01 and 0.05 mg/m^3 for both respirable and inhalable fraction, respectively as nickel meets the criteria for classification as carcinogenic (category 1A). Therefore, to reduce the risk, the FEEDAP Panel considers that the exposure of the users should be minimised.

The applicant provided a skin and eye irritation and skin sensitisation studies performed with the additive under assessment.

The skin irritation potential of the additive was investigated in New Zealand White rabbits using the Intracutaneous Reactivity Test performed according to ISO-10993-10.[20] The results of the study indicated that the polar as well as the non-polar extracts of the additive are not irritant to the skin.

The eye irritation potential of the additive clinoptilolite of sedimentary origin was investigated in New Zealand White rabbits in accordance with Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 405[21] which showed that the additive is not an eye irritant (UN-GHS 'No Category').

The skin sensitisation potential of the additive was tested in a study performed according to OECD TG 406 (Guinea pig Maximisation test, modified according to Maurer & Hess),[22] which showed that the additive is not skin sensitiser.

The skin sensitisation potential of the additive was further tested in another study performed according to OECD TG 406 (Guinea pig using the Magnusson-Kligman Method)[23] which confirmed that the additive is not a skin sensitiser.

However, considering the presence of nickel, the additive should be considered a skin and respiratory sensitiser.

3.2.4.1 | *Conclusions on safety for the user*

The additive clinoptilolite of sedimentary origin is not a skin nor an eye irritant, but should be considered a skin and respiratory sensitiser. Inhalation and dermal exposure are considered a risk.

[19]Technical dossier/ Annex 3.1.1.
[20]Technical dossier/ Annex_SIn_II_04.
[21]Technical dossier/ Annex_SIn_II_01.
[22]Technical dossier/ Annex_SIn_II_02.
[23]Technical dossier/ Annex_SIn_II_03.

3.3 | Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

4 | CONCLUSIONS

The applicant provided evidence that the additive currently on the market complies with the existing conditions of authorisation.

The Panel concludes that the additive clinoptilolite of sedimentary origin remains safe for all animal species, consumers and the environment under the authorised conditions of use.

Regarding user safety, the additive is not a skin nor an eye irritant but should be considered a skin and respiratory sensitiser. Inhalation and dermal exposure are considered a risk.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

5 | RECOMMENDATIONS

The FEEDAP Panel recommends that the units in the entry under provisions 'Total quantity of clinoptilolite of sedimentary origin from all sources shall not exceed the maximum content of 10,000 mg' should be corrected and that this provision is extended to all clinoptilolites, not only to that of sedimentary origin: 'Total quantity of clinoptilolite from all sources shall not exceed the maximum content of 10,000 mg/kg complete feed'.

ABBREVIATIONS

AES–ICP	Inductively coupled plasma–atomic emission spectrometry
CAS	Chemical Abstracts Service
ELS	Extensive literature search
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
GLP	Good Laboratory Practices
ISO	International Organization for Standardization
MNBN	Micronucleated binucleate cells
nDL-PCBs	non-dioxin-like Pcbs
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
PCBs	Polychlorinated biphenyls
PCDDs	Polychlorinated dibenzo-*P*-dioxins
PCDFs	Polychlorinated dibenzofurans
TEM	Transmission electron microscopy
TG	Test Guideline
UB	Upper bound
WHO	World Health Organization
XRD	X-ray diffraction

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REQUESTOR

European Commission

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PANEL MEMBERS

Roberto Edoardo Villa, Giovanna Azimonti, Eleftherios Bonos, Henrik Christensen, Mojca Durjava, Birgit Dusemund, Ronette Gehring, Boet Glandorf, Maryline Kouba, Marta López-Alonso, Francesca Marcon, Carlo Nebbia, Alena Pechová, Miguel Prieto-Maradona, Ilen Röhe and Katerina Theodoridou.

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