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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa for all animal species (Italiana Zeoliti s.r.l.)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa as a technological additive (functional group: anticaking) for all animal species. The additive is specified to contain not less than 50% of zeolites, namely phillipsite, chabazite and analcime. Neapolitan Yellow Tufa originates from the volcanic activity of Campi Flegrei, Italy. According to the conventional risk assessment, due to a lack of adequate data, the safety of the additive for the target species cannot be established. Based on current knowledge, there is no indication of substantial absorption of the components of the additive and, therefore, of concern for the consumer. The additive poses a risk by inhalation. It is not irritant to the skin. The Panel cannot conclude on the eye irritancy and on the dermal and respiratory sensitisation potential of the additive. As no suitable data in line with the requirements of the Guidance on risk assessment of nanomaterials were provided by the applicant, the potential risks associated with the presence of nanoparticles for the target species, the consumer and the user could not be assessed. The additive is safe for the environment. The additive is considered to be efficacious in feedingstuffs for all animal species at 20,000 mg/kg complete feed.

KEYWORDS

anticaking, efficacy, safety, technological additives, zeolites

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1 | INTRODUCTION

1.1 | Background and terms of reference

Regulation (EC) No 1831/20031 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 I.Z. Italiana Zeoliti s.r.l.[1] for the re-evaluation of the additive consisting of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa when used as a feed additive for all animal species (category: technological additives; functional group: 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 23 January 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 feed additive consisting of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa when used under the proposed conditions of use (see Section 3.1.3).

1.2 | Additional information

The original application was submitted as a re-evaluation of natrolite–phonolite (E566). However, in line with the new information on the characterisation, the applicant requested to modify the specifications and to define the product under assessment as Zeolites [phillipsite–chabazite–analcime] ≥ 50%. The additive zeolites (≥ 50%), obtained from Neapolitan Yellow Tufa, is currently not authorised as a feed additive in the European Union.

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[2] in support of the authorisation request for the use of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa as a feed additive.

The dossier was received on 02 December 2014 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2014-00888.

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.[3]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of natrolite–phonolite is in line with the principles laid down in Regulation (EC) No 429/2008[4] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019),

[1] Via Pescarolo 2, Tronco 300, 40,108, Pigneto di Prignano S/S (MO); Italy.

[2] FEED dossier reference: FAD-2010-0061.

[3] The full report is available on the EU Science Hub website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0061_en

[4] 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.

Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021a), Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health (EFSA Scientific Committee, 2021b).

3 | ASSESSMENT

The additive under assessment, zeolites (≥ 50%), is obtained from Neapolitan Yellow Tufa and is intended to be used as a technological additive (functional group: anticaking agent) in feedingstuffs for all animal species.

3.1 | Characterisation

The additive zeolites (≥ 50%) is obtained by extraction of the Neapolitan Yellow Tufa volcanic rock (linked to the volcanic activity of Campi Flegrei, Italy) [redacted][5] [redacted] The applicant declares that no chemicals are used in the production process.

The additive is specified to contain not less than 50% zeolites, namely phillipsite, chabasite and analcime. Based on analysis by X-ray powder diffraction (XRPD), the other crystalline phases consist of feldspars (alkaline or alkaline earth metal tectosilicates), pyroxene (inosilicate of various metals mainly Fe and Mg), phyllosilicates such as biotite (mica group) and montmorillonite (smectite group). Limited levels of non-crystalline volcanic glass which has a silicate composition are also present. The only phase that is not silicate is calcite ($CaCO_3$).

The applicant submitted data on 16 batches[6] analysing the mineralogical composition of the additive with X-ray diffraction (XRD). The results are shown in Table 1. The applicant submitted data on the mineralogical composition for five additional batches.[7] However, the analytical report indicated limitations of the method used and acknowledged that the results might be unreliable. Therefore, these data were not considered for the assessment.

TABLE 1 Mineralogical composition (%) of the additive zeolites (≥ 50%).

Mineral component	Mean (%)	Range (%)
Zeolites		
Phillipsite	32.4	12–44
Chabazite	21.7	10–43
Analcime	1.81	0–4
Total	**55.9**	**47–68**
Feldspar	22.7	12–39
Quartz	–	n.d.–1.2[b]
Others[a]	21.5	9–36

Abbreviation: n.d., not detected.

[a]Others: pyroxene, mica, smectite, albite, muscovite, amorphous.

[b]Only detected in one batch.

The average content of zeolites (phillipsite, chabasite and analcime) in all batches was ≥ 50%, thus compliant with the specifications, except for one batch showing 47.1%. The Panel notes that quartz was only detected in one batch out of the 16 analysed, with a content of 1.2%.

The elemental composition of the additive was analysed in seven batches[8] by means of X-ray fluorescence (XRF). The results expressed as the respective oxides are shown in Table 2.

[5]Technical dossier/Section II/Annex II_3_2.

[6]Technical dossier/Section II/Annex_II_1_3 and SIn_Feb18/daGennaro_2015b.

[7]Technical dossier/SIn_Reply(3)/Annex_5.

[8]Technical dossier/SIn_Feb18/daGennaro_2015b and SIn_Reply(3)/Annex_5.

TABLE 2 Average elemental composition of the additive zeolites (≥50%) expressed as respective oxides and loss on ignition.

Element[1]	Mean (%)	Range (%)
SiO_2	54.7	54–56
Al_2O_3	15.2	15–16
K_2O	6.10	5.8–7.3
CaO	4.20	3.6–4.5
Fe_2O_3	3.9	3.6–4.2
MgO	1.1	0.7–1.3
Na_2O	1.00	0.9–1.3
TiO_2	0.48	0.4–0.5
F	0.22	n.d.–0.4
MnO	0.15	0.1–0.2
Others[2]	< 0.50	–
Loss on ignition	12.7	10–15

[1]Expressed as oxide.

[2]P_2O_5; SrO; ZrO_2; BaO; Rb_2O; Cl; CeO_2; SO_3; V_2O_5; ZnO.

The analysis of cadmium, lead, mercury, fluorine and arsenic[9,10,11] showed average values (in mg/kg) of 0.13 (< 0.01–0.35; 16 batches) for cadmium, 16.7 (9.25–32.0; 16 batches) for lead, 0.04 (< 0.01–0.1; 16 batches) for mercury, 5.05 (< 0.02–14.8; 15 batches) for arsenic and 33.65 (2.23–89.4; 10 batches) for fluorine. Contents of other elements were also given: zinc (average = 13.5 mg/kg; 10 batches), copper (average = 9.74 mg/kg; 4 batches) and calcium (average = 8.38 mg/kg; 4 batches). Nickel was not detected (3 batches); however, the Panel notes that analysis was performed by XRF and the limit of quantification (LOQ) of the method is very high (30 mg/kg) and does not allow to exclude the presence of nickel in the additive.[12]

Dioxins and the sum of dioxins plus dioxin-like PCBs concentrations/levels were 0.09 ng WHO-PCDD/F-TEQ/kg and 0.15 ng WHO-PCDD/F-PCB-TEQ/kg in eight batches of the additive; non-dioxin-like PCBs ranged from 0.04 to 0.54 µg/kg additive (six batches analysed).[13]

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns, except for the potential presence of nickel, which will be addressed in the user safety section.

No data on the possible interference of the additive with the analytical determination of mycotoxins was provided.

3.1.1 | Physical properties of the additive

The additive is an inert, pale yellow, odourless powder, insoluble in water, with a melting point above 1473 K. The bulk density is 1110 kg/m^3 (range 1020–1160), the apparent density is 2260 (range 2.24–2.28) kg/m^3, and the true density is between 2250 and 2290 kg/m^3.[14] The cation exchange capacity (CEC) ranges between 1.8 and 2.2 meq/g.

The dusting potential of three batches of the additive was determined using the Stauber-Heubach method and showed values on average of 2513 mg/m^3 (range 1885–2850 mg/m^3) (mg airborne dust per m^3 of air).[15] The dust fractions generated during the experiment were analysed for particle size distribution by laser diffraction method; the results showed that on average 79.5% (v/v) of the particles are below 10 µm, and all of them are below 50 µm.[16]

It was noted that the particle size data made available did not allow the risk assessors to exclude the presence of small/nanoparticles as foreseen in the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021a). Therefore, the applicant was requested to provide information by choosing any of the appraisal routes as indicated by the aforementioned guidance document. The applicant submitted an analysis of the particle size using transmission electron microscopy (TEM)

[9]Technical dossier/Section II/Annex_II_1_3.

[10]Technical dossier/SIn Feb18/de Gennaro, 2015b.

[11]Technical dossier/SIn_Reply(3)/Annex_5.

[12]Technical dossier/SIn_310323/Annex_5.

[13]Technical dossier/Section II/Annex_II_1_4_2 and SIn Feb18/de Gennaro, 2015b.

[14]Technical dossier/Section II/Annex_II_1_5.

[15]Technical dossier/SIn Feb18/Annex_II_1_5_1.

[16]Technical dossier/SIn Feb18/Annex_II_1_5_2.

following the criteria of the Guidance on technical requirements (EFSA Scientific Committee, 2021a).[17] The applicant reported that 'the material is extremely polydisperse and heavily agglomerated. It is likely that the finer particles showed a different agglomeration behaviour'. The quantitative TEM analysis performed in five batches showed that 43%–74% of the particles (number-based) had the minimum Feret diameter < 100 nm. Thus, the data confirmed that the additive under assessment contains small particles including nanoparticles (> 10% of the particles of the sub-500 nm fraction have at least one external dimension smaller than 250 nm).

3.1.2 | Stability and homogeneity

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

For technological additives, evidence of homogenous distribution is not considered necessary if the efficacy of the additive is demonstrated. The applicant provided evidence of the homogenous distribution in feed in the efficacy studies done with several feedingstuffs/feed materials. The studies are described in the efficacy section (see Section 3.3).

In addition, the applicant provided a homogeneity study in 10 subsamples of two feedingstuffs: a ruminant premixture and a complete feed for weaned piglets[18] using the loss on ignition method as the evaluation endpoint. The percentage of ashes was measured in each subsample, and the coefficient of variation (CV) per feedingstuff was calculated. In the ruminant premixture and pig feed, the percentage of ashes ranged between 14.6%–15.3% and 7.3%–7.4%, and the CV was 1.37% and 1.59%, respectively.[19]

3.1.3 | Conditions of use

The additive is intended for use in feed for all animal species at a minimum use level of 10,000 mg/kg and a maximum of 25,000 mg/kg complete feed.

3.2 | Safety

The Panel notes that the additive contains nanoparticles and no suitable data in line with the requirements of the Guidance on risk assessment of nanomaterials (EFSA Scientific Committee, 2021b) were provided by the applicant. Considerations of the implications of the presence of nanoparticles on the safety assessment are made at the end of the section.

The studies submitted in the dossier considering a conventional risk assessment are described below.

3.2.1 | Genotoxicity studies

The applicant focused the investigation on the assessment of the potential genotoxicity of the soluble part of the additive (if any) by testing a homogenous suspension of the additive.

The additive was evaluated in a bacterial reverse mutation test in the tester strains of Salmonella Typhimurium TA98, TA100, TA1535, TA1537 and TA102, both in the presence and absence of an exogenous mammalian metabolic activation system (S9), in compliance with OECD Testing Guideline (TG) 471 and claimed to be good laboratory practice (GLP) compliant.[20] The test item was mixed directly in ultrapure water at 50 mg/mL and formed a uniform suspension. Mild precipitation was observed at the highest tested concentration of 5000 µg/plate. No inhibition of background lawn (cytotoxicity) and reduction in the number of revertant colonies were observed up to 5000 µg/plate, which was the maximum concentration tested. Two experiments were performed. The plate incorporation method was applied in the first experiment, and the pre-incubation method in the second one. No significant increase in revertant colony count was observed both in the presence and absence of metabolic activation in any experimental condition when compared to the vehicle control. The positive controls used in the study exhibited a significant increase in the mean number of revertant colony frequencies, indicating the sensitivity of the method and the functionality of the metabolic activation system. The FEEDAP Panel concludes that the soluble part of the test item, if any, of a water suspension of the test item does not induce gene mutations under the experimental conditions employed in the study.

The additive was evaluated in an in vitro Mammalian Cell Micronucleus Test in Human Peripheral Blood Lymphocytes that was performed according to OECD TG 487 and claimed to be performed GLP compliant.[21] The additive was dispersed in a complete growth medium (RPMI). No precipitation or pH alteration was found at 2 mg/mL. Based on the results of a preliminary cytotoxicity test, three concentrations were selected (i.e. 500, 1000, 2000 mg/mL) for the analysis of

[17]Technical dossier/SIn_Reply(3)/Annex_5.

[18]Feedingstuff composition: Ruminants: soybean meal 44%, sunflower meal, soybean hulls; Pigs: corn meal, soybean meal 44% and limestone.

[19]Technical dossier/Section II/Annex II_4_2.

[20]Technical dossier/SInJun21/Annex_1.

[21]Technical dossier/SInJun2021/Annex_2.

micronuclei in binucleated cells applying a short-term treatment (3+ 23 h of recovery) in the presence and in the absence of metabolic activation and continuous treatment (26 + 0 h of recovery) in the absence of metabolic activation. Cytochalasin B, blocking cytokinesis to obtain binucleated cells for the analysis of micronuclei, was added at the end of short-term exposure cultures and along with treatment for continuous exposure treatment cultures. Cytotoxicity up to 19% relative to the vehicle controls was observed at the highest concentration test after continuous treatment in the absence of metabolic activation, while levels lower than 17% were detected after short-term exposure. No significant increase in the frequency of micronuclei in binucleated cells was observed at any concentrations tested in any experimental condition. The FEEDAP Panel concludes that the soluble part of the test item (if any) of a water suspension of the test item in a culture medium did not induce structural and numerical chromosome aberrations in cultured human peripheral blood lymphocytes under the experimental conditions employed in the study.

Based on these results, the FEEDAP Panel concludes that the soluble part (if any) of the additive shows no genotoxic potential under the tested conditions. No conclusions can be drawn from the test results on the genotoxic potential of the particulate fraction of the suspension, since in the Ames test, particles do not penetrate the bacterial cell wall and the in vitro mammalian cell micronucleus test was performed without specific adaptations of the test design for the assessment of the particulate fraction.

3.2.2 | Safety for the target species

The applicant submitted one tolerance trial in chickens for fattening[22] and one in cattle for fattening[23] to support the safety for the target animals. The highest intended overdose level applied in both trials was ≤ 2× the maximum use level; however, a gross pathology examination of the organs of the animals at the end of the studies was not performed. It is also noted that several relevant blood parameters were not measured. Therefore, the Panel cannot perform a complete assessment of the safety of the additive for chickens for fattening and cattle for fattening. In the absence of adequate tolerance trials, the FEEDAP Panel cannot conclude on the safety of the additive for chickens and cattle for fattening. No information has been provided on any other target species. Therefore, the Panel cannot conclude on the safety of the additive for all animal species.

3.2.2.1 | *In vivo interactions*

An in vivo interaction/digestibility study was conducted as part of the tolerance study in chickens for fattening, in order to evaluate the interactions of zeolites (≥ 50%) with other components of the diet.[24]

A total of 504 1-day-old male chickens for fattening (Ross 308) were distributed in 36 pens and randomly allocated to three dietary treatments (12 replicates per treatment). Three basal diets (starter–from day 1 to 10; grower–from day 11 to 28; and finisher–from day 29 to 35) based on maize, wheat, soybean meal and rapeseed meal were either not supplemented (control) or supplemented with zeolites (≥ 50%) to provide 25,000 (1× maximum use level) or 50,000 (2×) mg of the additive/kg feed (confirmed by analysis). The experimental diets were offered for 35 days in a crumble (starter) or pelleted (grower/finisher) form, on an ad libitum basis, and contained lasalocid sodium as coccidiostat.

Excreta samples were collected between days 32 and 35 from 10 birds per treatment and pooled per animal. Feed and excreta samples were analysed for the content of dry matter, nitrogen, zinc, retinyl, thiamine and lasalocid sodium, and nutrient retention was calculated. No differences were observed in the utilisation of zinc, retinyl, crude protein and lasalocid sodium between treatments. A significantly higher thiamine retention was observed in the 2× group (93.3%) compared to the control (89.4%).

The results of the study suggest that zeolites (≥ 50%) will not interfere with the nutrient supply of animals.

3.2.3 | Safety for the consumer

Based on current knowledge and applying a conventional risk assessment, there is no indication of substantial absorption of the components of the additive. Therefore, the FEEDAP Panel concludes that the use of the additive in animal nutrition according to the conditions of use is of no concern for the consumer.

3.2.4 | Safety for the user

No inhalation toxicity study with the additive under assessment has been provided. Based on the dusting potential data available (up to 2850 mg/m^3), the FEEDAP Panel considered that the exposure of users through inhalation is likely.

The FEEDAP Panel notes that the additive may contain crystalline silica (up to 1.2%). Inhalation of crystalline silica is known to be hazardous and associated with an increased risk of lung cancer and the industrial disease, silicosis. The

[22]Technical dossier/Section III/Annexes III_1_1a/b/c.

[23]Technical dossier/Section III/Annex III_1_2.

[24]Technical dossier/SInFeb18/Annexes III_1_1a/b/c.

European Directive 2022/431 set an occupational exposure limit (OEL) of 0.1 mg/m^3 of air for respirable crystalline silica dust. The applicant submitted data on the dusting potential on three batches of the additive; however, data on the respirable fraction of the dust were not available. Therefore, the FEEDAP Panel used as a worst-case scenario the highest dusting potential data to calculate the content of silica present in the dust. The dust fraction of zeolites (≥ 50%) was up to (2850 mg/m^3), corresponding to 34 mg crystalline silica/m^3 dust.

No studies to investigate the potential of the additive to be an eye irritant or a skin sensitiser have been provided by the applicant.

The skin irritation potential of the additive was tested in an in vivo study performed according to OECD TG 404, which showed that the additive is not a skin irritant.[25]

In the absence of studies on skin sensitisation and due to the lack of reliable data on the possible presence of nickel in the additive, the FEEDAP Panel cannot conclude on the potential of the additive to be a dermal and respiratory sensitiser. Moreover, the FEEDAP Panel is not in the position to perform the exposure assessment to nickel by inhalation.

3.2.4.1 | *Conclusions on the safety for the users*

Zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa pose a risk by inhalation. It is not irritant to the skin. The FEEDAP Panel cannot conclude on the eye irritation and the dermal and respiratory sensitisation potential of the additive.

3.2.5 | Safety for the environment

The components of the additive are widely distributed in the environment. Therefore, it is not expected that the use of the additive in animal nutrition would adversely affect the environment.

3.2.6 | Specific considerations on the presence of nanoparticles and the safety assessment of the additive

Based on particle size data generated according to the Guidance on technical requirements (EFSA Scientific Committee, 2021a), the additive under assessment contains small particles including nanoparticles and should follow a nano-specific risk assessment as indicated by the EFSA SC Guidance on risk assessment of nanomaterials to be applied in the food and feed chain, human and animal health (EFSA Scientific Committee, 2021b).

The FEEDAP Panel noted that no data in line with the requirements of the Guidance on risk assessment of nanomaterials (EFSA Scientific Committee, 2021b) were provided by the applicant. Therefore, an assessment of the potential risks associated with the presence of nanoparticles could not be undertaken for the safety of target animals, consumers and users.

3.2.7 | Conclusions on the safety of the additive

According to the conventional risk assessment, due to a lack of adequate data, the safety of the additive for the target species cannot be established. Based on the current knowledge, there is no indication of substantial absorption of the components of the additive; therefore, there is no concern for the consumer. The additive poses a risk by inhalation. It is not irritant to the skin. The Panel cannot conclude on the eye irritancy and on the dermal and respiratory sensitisation potential of the additive.

As no suitable data in line with the requirements of the Guidance on risk assessment of nanomaterials (EFSA Scientific Committee, 2021b) were provided by the applicant, the potential risks associated with the presence of nanoparticles for the target species, the consumer and the user could not be assessed.

The additive is safe for the environment.

3.3 | Efficacy

One in vitro study was provided to support the efficacy as an anticaking in mash feeds of three animal species: cattle, pig and chicken.

The flowability of the three feeds supplemented with the additive at a concentration of 0 (control) and 20,000 mg/kg was determined by two different methods.[26]

In the first methodology followed, about 2 kg of each test feed was weighed and introduced in a laboratory silo. The time necessary to empty the silo was measured in seconds. The shorter the time for the silo to be emptied, the higher the flowability. Six subsamples per feed were tested.

[25]Technical dossier/Section III/Annex 12.

[26]Technical dossier/Section IV/Annex IV_1.

In the second, about 600 g of each feed was poured on a formica-coated wood flat laminate (600 × 200 mm). The laminate was raised by a hydraulic ram, and the angle at which the feed started to slide was recorded. The smaller the angle, the higher the flowability. Six subsamples per feed were tested.

The experimental data were statistically analysed with a generalised linear model, including the feed type, additive inclusion and the interaction among those as fixed effects. Means were compared with Dunnett's test for each feed type. The significance level was set at 0.05 (Table 3).

TABLE 3 Effect of the supplementation with zeolites (≥ 50%) on the flow time and slide angle of mash compound feeds for cattle, pig and chickens.

Feed (6 subsamples)	Zeolites (≥ 50%) (mg/kg)	Flow time (s)	Slide angle (°)
Cattle	0	95.3	22.3
	20,000	79.8[a]	20.6[a]
Pig	0	88.5	22.1
	20,000	77.2[a]	21.3[a]
Chicken	0	85.7	22.2
	20,000	70.8[a]	21.1[a]

[a]For each parameter and compound feed, the asterisk reflects significant differences between the supplemented feed and the control.

Based on the in vitro study submitted, the Panel concludes that the additive has the potential to be efficacious as an anticaking agent at 20,000 mg/kg in feed for all animal species.

4 | CONCLUSIONS

According to the conventional risk assessment, due to a lack of adequate data, the safety of the additive for the target species cannot be established. Based on the current knowledge, there is no indication of substantial absorption of the components of the additive and, therefore, of concern for the consumer. The additive poses a risk by inhalation. It is not irritant to the skin. The Panel cannot conclude on the eye irritancy and on the dermal and respiratory sensitisation potential of the additive.

As no suitable data in line with the requirements of the guidance on risk assessment of nanomaterials were provided by the applicant, the potential risks associated with the presence of nanoparticles for the target species, the consumer and the user could not be assessed.

The additive is safe for the environment.

The additive is considered to be efficacious in feedingstuffs for all animal species at 20,000 mg/kg complete feed.

5 | RECOMMENDATION AND REMARK

The additive should be specified as zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa linked to the volcanic activity of Campi Flegrei, Italy.

The FEEDAP Panel notes that the iron content of the product (average 1.9%) would limit the use of this additive in compound feedingstuffs, for which a maximum content of iron is set by EU legislation. This may raise issues for control authorities and feed compounders.

ABBREVIATIONS

CEC	cation exchange capacity
CV	coefficient of variation
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
GLP	Good Laboratory Practice
LOD	limit of detection
LOQ	limit of quantification
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure level
PCBs	Polychlorinated biphenyls
PCDD	polychlorinated dibenzo-*p*-dioxin
PCDF	polychlorinated dibenzofuran
SC	EFSA Scientific Committee
TEM	transmission electron microscopy

TEQ	toxic equivalent
TG	Test Guideline
XRPD	X-ray powder diffraction
XRF	X-ray fluorescence
WHO	World Health Organisation

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

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