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SCIENTIFIC OPINION

Safety of a feed additive consisting of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa for poultry for fattening or reared for laying/reproduction (Italiana Zeoliti s.r.l.)

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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, EFSA was asked to deliver a scientific opinion on the safety of a feed additive consisting of zeolites (≥ 50%) as a technological feed additive for poultry for fattening or reared for laying/reproduction. In 2024, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered an opinion on the safety and efficacy of the same additive. The Panel concluded that the use of the additive containing zeolites (≥ 50%) in animal nutrition is safe for the consumers and for the environment, and efficacious as an anticaking agent in feed for all animal species. The additive was not considered skin irritant. No conclusion could be reached on the eye irritancy and the respiratory and dermal sensitisation. Due to the dusting potential and its crystalline silica content, the additive was considered a risk by inhalation. In the current assessment, analytical data provided suggests that the inclusion of zeolites (≥ 50%) in poultry feed may interfere with the determination of aflatoxin B1. Regarding the target species, no conclusion could be drawn for poultry for fattening or reared for laying/reproduction. Based on the tolerance studies in chickens for fattening evaluated in the current assessment, the Panel concluded that the inclusion of zeolites (≥ 50%) at 12,500 mg/kg complete feed is safe for chickens for fattening or reared for laying/reproduction. No conclusion could be established on other poultry for fattening or reared for laying/reproduction.

KEYWORDS

anticaking agents, safety, technological additives, zeolites (≥ 50%)

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1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003 establishes the rules governing the Union authorisation of additives for use in animal nutrition; in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant is seeking a Union authorisation of the feed additive described in Table 1.

Table 1: Description of the additive in the application FEED-2024-31050 (FAD-2010-0061/SANTE 0025-2014).

TABLE 1 Description of the substances.

Category of additive	Technological additives
Functional group of additive	Anticaking agents
Description	Zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa
Target animal category	Poultry for fattening and reared for laying or reproduction
Applicant	Italiana Zeoliti s.r.l.
Type of request	New opinion – Request for scientific opinion pursuant to Article 29(1)(a) of Regulation (EC) No 178/2002

On 14.11.2023, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), in its opinion on the safety and efficacy of a feed additive consisting of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa for all animal species, could not conclude on the safety of the additive.

The European Commission gave the possibility to the applicant to submit supplementary information and data to complete the assessment and to allow a revision of the EFSA's opinion.

On 29.07.2024 the applicant requested a partial withdrawal of the application to reduce its scope to chickens for fattening and other poultry for fattening, which the Commission acknowledged in the letter Ares(2024)6044482 of 26.08.2024.

However, on 13.02.2025, when submitting supplementary information, the applicant asked to have the scope extended to poultry reared for laying/breeding, which the Commission can accept, considering that no formal action has been taken yet following the initial request of the applicant of 29.07.2024.

The new supplementary information and data have been transmitted by the applicant using the E-Submission Food Chain Platform (application number FEED-2024-31050).[1]

In view of the above and in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002, the European Commission requests EFSA to deliver a new scientific opinion on a feed additive consisting of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa for poultry for fattening and reared for laying or reproduction under the conditions of Regulation (EC) No 1831/2003, based on the supplementary information and data submitted by the applicant.

1.2 | Additional information

The additive consists of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa. It has not been previously authorised as a feed additive in the European Union.

EFSA issued one opinion on the safety and efficacy of this product when used in feed for all animal species (EFSA FEEDAP Panel, 2023).

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[2] to a previous application on the same product.[3] The dossier was received on 18/3/2025 and the general information and supporting documentation are available on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2025-00214.

[1]The E-Submission Food Chain Platform (https://webgate.ec.europa.eu/esfc).

[2]Dossier reference: FEED-2024-31050.

[3]Dossier reference: FAD-2010-0061.

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of zeolites (≥ 50%) obtained from Neapolitan Yellow Tufa is in line with the principles laid down in Regulation (EC) No 429/2008[4] and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b).

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 feed for poultry for fattening and poultry reared for laying or reproduction at a minimum use level of 10,000 mg/kg and a maximum of 25,000 mg/kg complete feed.

The additive is obtained by extraction of the Neapolitan Yellow Tufa volcanic rock (linked to the volcanic activity of Campi Flegrei, Italy). It is specified to contain not less than 50% zeolites, namely phillipsite, chabasite and analcime. The additive was characterised in the previous opinion (EFSA FEEDAP Panel, 2023). However, no data on the possible interference of the additive with the analytical determination of mycotoxins was submitted. In the previous assessment, the FEEDAP Panel concluded that the additive is safe for the consumers and the environment and that it was efficacious as an anticaking agent in feed for all animal species (EFSA FEEDAP Panel, 2023). The additive was not considered a skin irritant. However, the Panel could not conclude on the eye irritation and the respiratory and dermal sensitisation potential. Due to the dusting potential and its crystalline silica content, the additive was considered a risk by inhalation. Regarding the safety for the target species, the applicant submitted one tolerance trial in chickens for fattening. However, the study was not considered adequate due to several limitations on the study design and reporting. Therefore, no conclusion could be reached on the safety for chickens for fattening or any other poultry for fattening or reared for laying/reproduction.

3.1 | Characterisation

3.1.1 | Interference of the additive with the analysis of mycotoxins in feed

The applicant evaluated the capacity of the additive to interfere with the analytical determination of aflatoxin B1, zearalenone, fumonisins B1/B2, ochratoxin A and deoxynivalenol in poultry feed supplemented with 20,000 mg zeolites/kg complete feed.[5] Aflatoxin B1 was introduced at the final concentration of 0.02 mg/kg, zearalenone at 0.5 mg/kg, fumonisins B1/B2 at 20 mg/kg, ochratoxin A at 0.1 mg/kg and deoxynivalenol at 5 mg/kg of feed. No effects on the analytical determination of zearalenone, fumonisins B1/B2, ochratoxin A and deoxynivalenol in feed were observed with the addition of the additive in complete feed. However, the analysis of aflatoxin B1 showed a 25% lower content in the feed supplemented with the additive (10.2 μg/kg) compared to the control (13.8 μg/kg). The data provided suggests that the addition of zeolites (≥ 50%) in poultry feed may interfere with the analytical determination of aflatoxin B1.

3.2 | Safety for the target species

The applicant provided one study in chickens for fattening to support the safety for the target species.

Tolerance trial in chickens for fattening[6]

A total of 720 Ross 308 one-day-old male chickens for fattening were distributed across 36 floor-pens, with 20 animals per pen, and randomly allocated to three experimental groups (12 replicates per group). Two basal diets (starter, from days 1 to 21; finisher, from days 22 to 35) based on maize, wheat and soybean meal were either not supplemented (control) or supplemented with the additive to provide 25,000 (1× maximum use level) or 50,000 (2×) mg per kg complete feed. The content of the additive in the feed was analysed using iron and aluminium as markers; the Panel notes that the analytical results showed values approximately 50% lower than the intended levels (see Table 2). The experimental diets were offered ad libitum in pelleted form for 35 days.

The health status and mortality were checked daily, and dead animals were weighed and necropsied. The birds were weighed at the start of the trial. Thereafter, the average pen body weight and feed intake were recorded on days 21 and 35. The average daily feed intake, average daily gain and feed-to-gain ratio were calculated and corrected for mortality. At day

[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.

[5]Annex_II.Sin.1_Mycotoxins.

[6]Study Report_Male Broilers Tolerance trial.

35, two birds per pen were randomly selected, and the blood was sampled and analysed for haematology[7] and biochemistry.[8] At the end of the experiment, one bird per pen was randomly selected, killed, evaluated for gross pathology, and the organs[9] were weighed.

Productive performance, blood data and organ weights were analysed using a generalised linear model, with diet and block (location in the room) as fixed effects. The experimental unit was the pen for productive performance, and the individual animal for blood and organ parameters. When differences between groups were observed, means were compared with the Tukey test. For the proof of tolerance, the overdose group (2×) was tested for non-inferiority compared to the reference groups (control and use level), with comparisons of average daily gain (Δ = 2.24 g) and average daily feed intake (Δ = 3.83 g). The significance level was set at 0.05.

Overall mortality (including culling) did not differ between groups. The lower 90% confidence intervals of the average daily weight gain (−4.61 g) and feed intake (−3.92 g) of the overdose (2×) group were below the respective non-inferiority margins established (Δ = 2.24 g and 3.83 g, respectively). Therefore, the non-inferiority of the overdose compared to the control group could not be demonstrated. The results of the same parameters showed that the use level was not inferior to the control. The inclusion of zeolites in the chicken's diet resulted in a dose-dependent reduction of the final body weight, average daily weight gain, average daily feed intake and an increase in the feed-to-gain ratio. The final body weight, average daily gain, and feed intake were significantly lower at 2× than the control, resulting in a worse feed-to-gain ratio (Table 2).

TABLE 2 Effects of the dietary supplementation of chickens for fattening with zeolites (≤ 50%) on selected parameters and the estimated analytical content in feed.

	Control	1×	2×
Zeolites (≥ 50%) (mg/kg complete feed)*			
Intended (starter/grower)	0	25,000	50,000
Analysed content of Al/Fe	312/372	1315/748	2425/1185
Estimated content of the additive	–	12,313/12,231	25,932/26,482
Mortality/culling (%)	3.8/1.7	5.0/0.8	3.3/1.3
Performance parameters			
Final body weight (g)	2698[a]	2672[a]	2570[b]
Average daily gain (g)	74.9[a]	74.3[a]	71.6[b]
Average daily feed intake (g/bird)	107.1[ab]	107.4[a]	104.9[b]
Feed-to-gain ratio	1.43[b]	1.45[ab]	1.47[a]
Blood parameters			
Amylase (IU/L)	541[a]	452[ab]	311[b]
Total bilirubin (mg/dL)	0.08[a]	0.07[ab]	0.06[b]
Organ weight (% body weight)			
Proventriculus	0.37[b]	0.38[b]	0.49[a]

*Calculated based on the analytical content of Fe and Al in the supplemented diets with respect to the control one, considering the content of both minerals in the batch of the additive used for the trial (values shown are the average of the starter and finisher diets).

[a,b]Different superscripts in a row mean significant differences ($p < 0.05$).

Regarding the blood data, compared with the control group, dietary supplementation with zeolites resulted in a dose-dependent reduction in serum amylase activity and bilirubin concentration, with a significant difference at 2× compared to the control. The values of both parameters remained within normal physiological ranges for healthy chickens. The Panel did not consider these effects adverse.

The relative organ weight of the proventriculus showed a dose-dependent increase with higher levels of the additive, becoming significant at 2× compared to the control. No gross pathological lesions were observed in the proventriculus of any group. However, an adverse effect could not be excluded, because no histopathological evaluation was performed in any of the tissues.

Based on the results of this tolerance trial, the Panel considers that including zeolites (≥ 50%) in the feed of chickens for fattening is safe at the intended use level with no margin of safety. Based on the analytical results for the test item in feed,

[7]Red blood cell count, haematocrit, haemoglobin, red blood cell distribution width, mean cell volume, mean cell haemoglobin, mean cell haemoglobin concentration, white blood cell count, lymphocytes, heterophils, fibrinogen, prothrombin time.

[8]Amylase, alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase, gamma-glutamyl transpeptidase, alkaline phosphatase, creatine kinase, sodium, potassium, chloride, calcium, phosphate, total protein, albumin, globulin, glucose, urea, uric acid, urea/uric acid ratio, cholesterol, creatinine, bilirubin, ovotransferrin, C-reactive protein.

[9]Liver, kidneys, spleen, adrenal gland, lung, stomach, pancreas, small intestine, colon, caecum, thymus, thyroid gland, heart, intestinal lymph nodes (caecal tonsils) and testes.

the conclusion is set at 12,500 mg/kg complete feed. This conclusion is extended to chickens reared for laying/reproduction. No conclusion can be established on other poultry for fattening or reared for laying/reproduction.

3.2.1 | Conclusions on safety for the target species

The additive consisting of zeolites (≥ 50%) is safe for chickens for fattening and for chickens reared for laying/reproduction at a maximum level of 12,500 mg/kg feed. No conclusion can be reached on the safety for other poultry for fattening or reared for laying/reproduction.

4 | CONCLUSIONS

The data provided suggests that the addition of zeolites (≥ 50%) in poultry feed may interfere with the analytical determination of aflatoxin B1.

The feed additive consisting of zeolites (≥ 50%) is safe for chickens for fattening and for chickens reared for laying/reproduction at a maximum level of 12,500 mg/kg feed. No conclusion can be reached on the safety for other poultry for fattening or reared for laying/reproduction.

ABBREVIATION

FEEDAP EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2025-00214

PANEL MEMBERS

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