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SCIENTIFIC OPINION

Safety of a feed additive consisting of sepiolite for all animal species (Sepiol S.A. and Tolsa S.A.)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety of sepiolite as a technological feed additive for all animal species. In 2022, 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 sepiolite used as a feed additive is safe for the consumers and the environment, and efficacious as a thickener-suspending agent, binder and anticaking agent in feed for all animal species under the proposed conditions of use. The additive was not considered an eye or skin irritant. However, it was considered a respiratory irritant, a respiratory and dermal sensitiser; owing to the dusting potential and its silica content, the additive was considered a risk by inhalation. Regarding the target species, in the previous Opinion, the Panel concluded on the safety of the additive for dairy ruminants. However, no conclusion could be drawn for all other species/categories. Based on the tolerance studies in chickens for fattening, weaned piglets and trout evaluated in the current assessment, and the one in dairy cows previously assessed, the Panel concluded that the inclusion of sepiolite at the maximum recommended level of 20,000 mg/kg complete feed is safe for all animal species.

KEYWORDS

all animal species, anticaking agent, binder, safety, sepiolite, thickener

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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 Community authorisation of additives for use in animal and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, Sepiol S.A./Tolsa S.A., represented by Erawan Consulting SARL, is seeking a Community authorisation of sepiolite as a technological additive for all animal species (Table 1).

TABLE 1 Description of the additive.

Category of additive	Technological additive
Functional group of additive	Binders, anticaking agents
Description	Sepiolite
Target animal category	All animal species
Applicant	Sepiol S.A./Tolsa S.A.
Type of request	New opinion

On 23.03.2022,[1] the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), in its opinion on the safety of a feed additive consisting of sepiolite for all animal species could not conclude on the safety of the product for target species/categories other than dairy ruminants.

The 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.

The new data have been received by the Commission on 30.08.2023 on the e-submission food chain platform (application number FEED-2023-18293).

In view of the above, the Commission asks EFSA to deliver a new opinion on sepiolite as technological feed additive for all animal species based on the supplementary information and data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

1.2 | Additional information

Sepiolite is authorised as a binder, anticaking agent and coagulant for all animal species, subject to re-evaluation.

EFSA has adopted one opinion on the safety and efficacy of sepiolite for all animal species as a technological additive (thickener, binder and anticaking) (EFSA FEEDAP Panel, 2022), one in which sepiolite was incorporated as a preparation in combination with bentonite as 'substances for reduction of the contamination of feed by mycotoxins' for all animal species (EFSA FEEDAP Panel, 2013), and another in combination with kieselguhr (diatomaceous earth) 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 25/9/2023, and the general information and supporting documentation are available on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00638.

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, other scientific reports and experts' (elicitation) knowledge, to deliver the present output.

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 sepiolite in animal feed are valid and applicable to the current application.[4]

[1]The Mandate contained a typo in which the adoption date was indicated as 23.3.2023.

[2]Dossier reference: FEED-2023-18293.

[3]Dossier reference: FAD-2010-0365.

[4]The evaluation report is available on the EU Science Hub https://joint-research-centre.ec.europa.eu/document/download/dfeb4848-d0d6-4147-be14-2ca496a773d4_en?filename=finrep-fad-2010-0365-sepiolite.pdf.

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of sepiolite is in line with the principles laid down in Regulation (EC) No 429/2008[5] 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) and Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021).

3 | ASSESSMENT

The product under assessment is a mixture of clay and non-clay fractions containing a minimum of 60% sepiolite (mineral), intended to be used as a technological additive (functional groups (e) thickeners, (g) binders and (i) anticaking agents) at a maximum recommended level of 20,000 mg/kg in complete feed for all animal species. The additive would be referred to as Sepiolite.[6]

In the previous assessment, the Panel concluded that the additive is safe for the consumers and the environment and that it was efficacious as a thickener, binder and anticaking agent in feed for all animal species under the proposed conditions of use (EFSA FEEDAP Panel, 2022). The additive was not considered an eye or skin irritant. However, it was considered a respiratory irritant and a respiratory and dermal sensitiser. Due to the dusting potential and its silica content, the additive was considered a risk by inhalation.

The Panel could not conclude on the safety of the product for target species/categories other than dairy ruminants. The applicant has provided new data to address the gaps identified in the previous opinion, which are assessed below.

3.1 | Characterisation of the additive

The FEEDAP Panel has already assessed the characterisation of the product in terms of its mineralogical and chemical composition, manufacturing process, and physicochemical properties (EFSA FEEDAP Panel, 2022). The applicant submitted additional particle size analysis data using scanning electron microscopy (SEM).[7] The analysis showed that a surface structure can be observed in the aggregates composed of elongated constituent particles, which suggests that the material is nanostructured with component particles likely with at least one external dimension smaller than 250 nm. Due to shortcomings identified in the methodology, the data did not allow to determine the particle size distribution of the fraction of small particles. In particular, the dispersion protocol was not in line with the methodology indicated 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, 2021).

3.2 | Safety for the target species

In the context of a previous application, the applicant provided four tolerance trials: two in chickens for fattening, one in weaned piglets and one in dairy cows (EFSA FEEDAP Panel, 2022). The two tolerance trials in chickens and the one in weaned piglets showed limitations in the experimental design and were not considered further in the assessment. Based on the tolerance study in cows, the Panel concluded that the additive is safe for dairy cows at the maximum proposed use levels of 20,000 mg/kg complete feed, with a margin of safety of 2.5. This conclusion was extrapolated to other dairy ruminants.

In the current application, the applicant submitted three tolerance trials to support the safety for the target species: one in chickens for fattening, one in weaned piglets and one in trout.

3.2.1 | Safety for chickens for fattening

A total of 960 one-day-old male chickens for fattening (Ross 308) were distributed in 48 pens of 20 chickens each, randomly allocated into four groups (12 replicates per treatment).[8] Three basal diets (starter, from days 1 to 10; grower, from days 11 to 21; and finisher, from days 22 to 35) based on maize and soybean meal were either not supplemented (control) or

[5]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.

[6]Throughout the document, the term 'sepiolite' has been reported in capital letters when it refers to the additive itself and in lower case letters when it refers to the mineral contained in the additive.

[7]Annex_RFI_1_Q2_8 SEM_Tolsa, Annex_RFI_1_Q2_9 SEM_Sepiolsa.

[8]Annex_SIn3_2 B-695 final report.

supplemented with sepiolite at 20,000 (1× maximum use level), 50,000 (2.5×) or 100,000 (5×) mg/kg complete feed. The content of the additive in the feed was analysed using magnesium as a mineral marker, which confirmed the intended inclusion rates of the additive.[9] The experimental diets were offered ad libitum in a crumble (starter) or pelleted (grower/finisher) form for 35 days.

The animals' health status and mortality were checked daily, and the most likely cause of death or reason for culling was recorded. Birds were individually weighed at the start of the trial (day 1). After that, the average pen body weight and feed intake were recorded on days 10, 21 and 35, and the average daily feed intake, the average daily weight gain and the feed-to-gain ratio were calculated for the whole period and corrected for mortality. On days 35 and 37, blood samples were obtained from two birds per pen (one bird sampled per day) and analysed for haematology[10] and biochemistry.[11] The same birds were killed, and the organs[12] were evaluated for gross pathology. The liver, kidneys, spleen, and heart weights were recorded.

The zootechnical performance, blood data and organ weights were analysed with a generalised linear model, considering the diet and block (pen lane within the experimental room) as fixed effects. Polynomial contrasts were also assessed. Mortality data were analysed with non-parametric testing (Kruskal–Wallis/Wilcoxon). The experimental unit was the pen for zootechnical performance and the individual animal for blood and organ traits. When differences were observed, group means were compared with Tukey's test. The significance level was set at 0.05.

The chickens' health was good throughout the trial. The overall mortality rate was in line with commercial standards (< 2.1%) and was unrelated to the additive supplementation. No significant differences on any zootechnical parameter were observed for the overall period at any supplemented group compared to the control (control values for final body weight = 2540 g; average daily weight gain = 71.4 g; average daily feed-intake = 100.8 g; feed-to-gain ratio = 1.41). Regarding the blood data, a significant dose-dependent linear effect was observed related to the additive supplementation for lower cholesterol (111, 107, 105 and 95 mg/dL, for control, 1×, 2.5× and 5×, respectively) and higher prothrombin time (137, 143, 137 and 183 s), showing a significantly higher time in the 5× group compared to control. The reduction of serum cholesterol was not considered an adverse effect of the additive. In the case of the prothrombin time, the Panel considered that the effect on this parameter alone, without any evident impact on animal health (e.g. petechiae, haemorrhages), is not enough to consider it an adverse effect. No other significant difference was observed between the supplemented groups and control in any blood haematology or biochemistry parameter.

The liver and kidney relative weights showed a significantly linear effect related to the supplementation with the additive (increased dose response for the kidneys and decreased dose response in the case of the liver). In the kidneys, the relative weight in the 5× group (0.65%) was significantly higher than the control group (0.59%). No gross pathology lesions and/or effects on blood-related parameters were observed in the liver or kidneys of any group. However, an adverse effect could not be excluded as no histopathology evaluation was performed in any of the tissues.

Based on the results of the tolerance trial, the Panel considers that including sepiolite in the feed of chickens for fattening is safe at the maximum use level proposed of 20,000 mg/kg complete feed, with a margin of safety of 2.5.

3.2.2 | Safety for weaned piglets

A total of 144 28-day-old Piétrain × (Landrace × Large White) weaned piglets (average initial BWt: 8.7 kg) were blocked based on initial body weight and distributed in 36 pens (two males and two females per pen), which were randomly allocated to four experimental groups (9 replicates per group).[13] Two basal diets (pre-starter from days 1 to 14 and starter from days 15 to 42) based on barley, maize and soybean meal were either not supplemented (control) or supplemented with sepiolite at 20,000 (1× maximum use level), 50,000 (2.5×) or 100,000 (5×) mg/kg complete feed. The content of the additive in the feed was analysed using magnesium as a mineral marker, which confirmed the intended inclusion rates of the additive.[14] The experimental diets were offered ad libitum in pelleted form for 42 days.

The piglets' health status and mortality were checked daily, and the most likely cause of death or reason for culling was recorded. Piglets were individually weighed at the start of the trial (day 1). After that, average pen body weight and feed intake were recorded on days 7, 14, 28 and 42, and average daily feed intake, average daily weight gain and feed-to-gain

[9]Concentration of magnesium in the starter/grower/finisher diets (g/100 g feed): Control = 0.19/0.17/0.16; 1× = 0.44/0.43/0.43; 2.5× = 0.80/0.82/0.83; 5× = 1.49/1.53/1.41, corresponding to a calculated content of sepiolite of 0/0/0, 19,800/20,400/21,600, 52,200/51,100/53,000 and 103,500/105,800/100,200 mg/kg feed for the control, 1×, 2.5× and 5× groups, respectively.

[10]Red blood cell count, haemoglobin, packed cell volume, mean cell volume, mean cell haemoglobin concentration, platelets, white blood cell count, white blood cell differentials (lymphocytes, monocytes, eosinophils, basophils, segment neutrophils, banded neutrophils) and prothrombin time.

[11]Alanine aminotransferase, amylase, alkaline phosphatase, aspartate aminotransferase, creatine phosphokinase, gamma-glutamyltranspeptidase, lactate dehydrogenase, bilirubin, creatinine, cholesterol, albumin, total globulins, total protein, glucose, uric acid, sodium, potassium, chloride, calcium, phosphate, magnesium and iron.

[12]Liver, kidneys, spleen, heart, adrenal gland, lungs, gizzard, proventriculus, crop, pancreas, small intestine (duodenum), colon, caecum, thymus, thyroid gland, Bursa of Fabricius, testes.

[13]Annex_Sln3_1 P-760bis_Final Report.

[14]Concentration of magnesium in the starter/grower/finisher diets (g/100 g feed): C = 0.19/0.17/0.16; 1× = 0.44/0.43/0.43; 2.5× = 0.80/0.82/0.83; 5× = 1.49/1.53/1.41, corresponding to an average calculated content of sepiolite of 0, 19,600, 49,400 and 98,500 mg/kg feed for the control, 1×, 2.5× and 5× groups, respectively.

ratio were calculated for the whole period and corrected for mortality. On days 1 and 43, blood samples were obtained from two animals per pen (one male and one female) and analysed for haematology[15] and biochemistry.[16] Two piglets per pen were killed, and the organs[17] were evaluated for gross pathology. The weight of the liver, spleen, lungs, and kidneys were recorded.

All experimental data were analysed with a generalised linear model, considering the diet and the block (based on initial body weight) as fixed effects. The experimental unit was the pen. When differences were observed, group means were compared with Tukey's test. The significance level was set at 0.05.

Only one piglet died (2.5× group) during the trial. No significant differences on any zootechnical parameter were observed for the overall period at any supplemented group compared to the control (control values for final body weight = 30.6 kg; average daily weight gain = 520 g; average daily feed intake = 759 g; feed-to-gain ratio = 1.46).

Regarding the blood haematology, no differences among groups were observed in any parameter, except for platelets, for which the control group showed a significantly lower concentration (324×10^3/mL) than all the supplemented groups (431, 428, 488×10^3/mL for the 1×, 2.5× and 5× groups). Out of the biochemical parameters analysed, the serum urea concentration was lower in the 2.5× group (9.8 mg/dL) compared to the control (15.0 mg/dL). All values of the haematology and biochemistry parameters were within the physiological ranges of healthy growing pigs. The relative weight of liver, spleen, kidneys and lungs did not differ among experimental groups. No relevant findings were observed in any organ in the gross pathology evaluation.

Based on the results of the tolerance trial, the Panel considers that the inclusion of sepiolite in the feed of weaned piglets is safe at the maximum use level proposed of 20,000 mg/kg complete feed, with a margin of safety of 5.

3.2.3 | Safety for trout

A total of 480 juvenile undifferentiated rainbow trout (*Oncorhynchus mykiss*; 4 months old, initial BW 11.7 ± 0.1 g) were distributed in groups of 30 fish to sixteen 500-L tanks, which were randomly allocated to four experimental groups (representing four replicate tanks per group).[18] A basal diet based on fish meal, poultry meal and soy protein concentrate was either not supplemented (control group) or supplemented with sepiolite at 20,000 (1× maximum use level), 50,000 (2.5×) or 100,000 (5×) mg per kg/complete feed. The content of the additive in the feed was analysed using magnesium as a mineral marker, which confirmed the intended inclusion rates of the additive.[19] The experimental diets were fed ad libitum in pelleted form for 92 days.

The fish health status and mortality were checked daily, and the most likely cause of death or reason for culling was provided. On days 1, 44, 67 and 92, all trout were individually weighed (BW), length measured (L) and daily feed intake recorded. The Fulton's condition factor, average daily feed intake, average daily gain, specific growth rate and feed-to-gain ratio were calculated. At the end of the trial (day 92), blood from five trout per tank (20 fish per treatment) was sampled and analysed for haematology[20] and biochemistry.[21] Five fish per tank (20 per treatment) were killed, and the organs[22] were evaluated for gross pathology. The weight of the liver and spleen was recorded, and the hepatosomatic (HSI[23]) and splenosomatic (SSI[24]) indexes were calculated. Histopathology analysis was performed on the liver, spleen and intestinal tract of four fish per tank (16 per group).

All data were analysed with a one-way analysis of variance, with the diet as a fixed effect. The experimental unit was the tank for productive performance and visceral indexes (HSI/SSI), and the individual animal was used for blood. When differences were observed, group means were compared with the Bonferroni test. The significance level was set at 0.05.

Mortality was, on average, 4.2% (range from 2.5% to 5.8%) and was unrelated to the additive supplementation. The sepiolite supplementation of fish feed at all inclusion levels did not affect the final body weight (control = 216.2 g), final standard length (23.0 cm), specific growth rate (3.16% BW/day), total feed intake (167.9 g), and feed-to-gain ratio (0.83). The Fulton's condition factor showed a significant difference of the 5× group compared to the control (see Table 2). No

[15]Red blood cell count, haemoglobin, packed cell volume, mean cell volume, mean cell haemoglobin, mean cell haemoglobin concentration, platelets, white blood cell count, white blood cell differentials (lymphocytes, monocytes, eosinophils, basophils, segment neutrophils, banded neutrophils), fibrinogen and prothrombin time.

[16]Alanine aminotransferase, amylase, alkaline phosphatase, aspartate aminotransferas, creatine phosphokinase, gamma-glutamyltranspeptidase, lactate dehydrogenase, bilirubin, creatinine, cholesterol, albumin, total globulins, total protein, acute phase proteins, glucose, urea, sodium, potassium, chloride, calcium, phosphate, magnesium and iron.

[17]Liver, kidneys, spleen, heart, adrenal gland, lungs, stomach, pancreas, small intestine (duodenum), colon, caecum, thymus, thyroid gland, intestinal lymph nodes, ovaries/testes.

[18]Annex_SIn3_3 Sepiolite Trout Tolerance trial.

[19]Concentration of magnesium in the starter/grower/finisher diets (g/100 g feed): C = 0.19/0.17/0.16; 1× = 0.44/0.43/0.43; 2.5× = 0.80/0.82/0.83; 5× = 1.49/1.53/1.41, corresponding to an average calculated content of sepiolite of 0, 19,600, 49,700 and 99,300 mg/kg feed for the control, 1×, 2.5× and 5× groups, respectively.

[20]Haematocrit, haemoglobin, red blood count, mean corpuscular volume, mean corpuscular haemoglobin concentration, white blood cell differentials (neutrophils, lymphocytes, heterophils, monocytes) and thrombocytes.

[21]Albumin, non-protein nitrogen, glucose, total proteins, total globulins, creatinine, bilirubin, triglycerides, cholesterol, urea, phosphorous, iron, calcium, chloride, potassium, sodium, magnesium, alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase, gamma-glutamyltrasferase, alkaline phosphatase, cratine kinase, amylase, lipase.

[22]Skin lesions, fin erosions, heart, gills, liver, spleen, digestive tract (stomach, pyloric caeca, intestine), eyes and bones.

[23]HSI (%) = 100 × (Liver weight/final fish body weight).

[24]SSI (%) = 100 × (Spleen weight/final fish body weight).

differences were observed in the hepatosomatic and splenosomatic indexes between groups. The blood haematology and biochemistry analysis showed significant differences in several parameters, shown in Table 2.

TABLE 2 Results of Fulton's condition factor and the most relevant blood haematology and biochemistry parameters from the tolerance study in sepiolite-fed trout after 92 days.

Parameter	Control	1×	2.5×	5×
Fulton's condition factor[1]	1.71[b]	1.77[ab]	1.77[ab]	1.78[a]
White blood cells (cells/μL)	24,400[a]	18,320[ab]	14,635[b]	23,440[a]
Heterophils (cells/μL)	1.0[a]	0.3[a]	4.9[b]	0.9[a]
Thrombocytes (cells/μL)	47,250[a]	40,750[ab]	35,687[b]	43,050[a]
Alanine aminotransferase (U/L)	23.5[a]	17.5[ab]	12.0[b]	13.8[b]
Aspartate aminotransferase (U/L)	1135[a]	815.3[ab]	623.7[b]	679.7[ab]
Creatine kinase (U/mL)	24.4[a]	13.6[b]	10.5[b]	9.9[b]
Lactate dehydrogenase (U/L)	4889[a]	3550[ab]	3104[ab]	2954[b]

Different letters within the same row indicate statistical differences between groups ($P < 0.05$).
[1]Fulton's condition factor = $100 \times (BW/L^3)$.

The modifications of the white blood cell count, heterophils count, thrombocytes and aspartate aminotransferase did not show a clear pattern and were considered of limited relevance. The reduced activities in serum of the alanine aminotransferase, creatine kinase and lactate dehydrogenase were not considered an adverse effect. In all cases, absolute values remained within physiological ranges for trout. The gross pathology evaluation showed no anomalies and/or injuries in any examined fish, and histopathological evaluation of the liver, spleen and intestines revealed no treatment-related effects.

Based on the results of the tolerance trial, the Panel considers that the inclusion of sepiolite in the feed of trout is safe at the maximum use level proposed of 20,000 mg/kg complete feed, with a margin of safety of 5.

3.2.4 | In vivo interactions

An in vivo interaction/digestibility study was conducted in parallel to the tolerance trial in chickens for fattening to evaluate the interactions of sepiolite with other components of the diet.[25]

Forty-eight 1-day-old male chickens for fattening (Ross 308) were distributed in 16 cages in groups of three chickens and randomly allocated to two groups (8 cages per group).[26] Two basal diets (starter from day 1 to day 10 and grower from day 11 to day 18) based on maize and soybean meal were either not supplemented (control) or supplemented with sepiolite at 20,000 mg/kg complete feed (1× maximum use level) (confirmed by analysis). The experimental diets were offered ad libitum as crumbles (starter) or pellets (grower) for 18 days containing monensin as a coccidiostat. The health status, mortality and zootechnical performance were monitored during the experimental period. From days 16 to 18 of the experiment, excreta samples were collected and pooled per cage. The feed and excreta samples were analysed for the content of dry matter, nitrogen, manganese, tocopheryl esters (α-tocopherol and α-tocopherol acetate), riboflavin (vitamin B_2), pyridoxine (vitamin B_6) and monensin, and the nutrient retention calculated. The retention data were statistically analysed via a generalised linear model, with the cage as the experimental unit and the diet as a fixed effect. When differences were observed, group means were compared with Tukey's test. The significance level was set at 0.05. No significant differences were observed in the nitrogen and manganese retention. The supplementation of Sepiolite at the maximum use level showed significantly higher retention of tocopherol (65.7% vs. 81.1% in the control and 1×, respectively), riboflavin (42.0% vs. 52.3%) and pyridoxin (7.5% vs. 26.4%), and lower retention of monensin (99% vs. 94%).

The results of the study suggest that sepiolite will not interfere with the nutrient supply of animals.

3.2.5 | Safety for all animal species

The tolerance studies assessed in this and the previous opinion of the FEEDAP Panel (EFSA FEEDAP Panel, 2022) showed that the use of sepiolite in dairy cows, chickens for fattening, weaned piglets and trout up to the maximum proposed use level of 20,000 mg/kg complete feed is safe, with a margin of safety of at least 2.5. Considering that the safety of the additive has been demonstrated in four major target species with different metabolic capacities and with a similar margin of safety, the FEEDAP Panel concludes that the use of sepiolite at the maximum proposed use level of 20,000 mg/kg complete feed is safe for all animal species.

[25]Annex_SIn3_2 B-695 final report.
[26]The experiment started with three birds per cage. However, on day 10 of the experiment, one bird per cage was removed and two birds remained in the cage for the rest of the experiment.

3.2.6 | Conclusions on the safety for the target species

The Panel concludes that the inclusion of sepiolite at the maximum recommended level of 20,000 mg/kg of complete feed is safe for all animal species.

3.3 | Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation[27] and Good Manufacturing Practice.

4 | CONCLUSIONS

The use of sepiolite at 20,000 mg/kg complete feed is considered safe for all animal species.

ABBREVIATIONS

BW	body weight
DM	dry matter
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
HIS	hepatosomatic index
L	standard length
SSI	splenosomatic index

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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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[27]Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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