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SCIENTIFIC OPINION

Assessment of the feed additive consisting of bentonite for ruminants, poultry and pigs for the renewal of its authorisation (Biomin GmbH)

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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 renewal of bentonite as a technological feed additive in the functional group of substances for reduction of the contamination of feed by mycotoxins for ruminants, poultry and pigs. The applicant has provided evidence that the additive currently on the market complies with the existing conditions of authorisation. There is no evidence that would lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concluded that the additive remains safe for ruminants, poultry and pigs, consumers and the environment under the authorised conditions of use. Regarding user safety, the Panel concludes that bentonite is not irritant to the skin but is irritant to the eyes and should be considered a skin and respiratory sensitiser. Any exposure is considered a risk. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

KEYWORDS

bentonite, efficacy, safety, substances for reduction of the contamination of feed by mycotoxins, technological additives

CONTENTS

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 one year before the expiry date of the authorisation.

The European Commission received a request from Biomin GmbH[2] for the renewal of the authorisation of the additive consisting of bentonite, when used as a feed additive for ruminants, poultry and pigs (category: technological additives; functional group: substances for the reduction of the contamination of feed by mycotoxins).

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). The dossier was received on 15 November 2022 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00799. The particulars and documents in support of the application were considered valid by EFSA as of 14 June 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 bentonite, when used under the proposed conditions of use (see **Section 3.1.4**).

1.2 | Additional information

Bentonite is currently authorised as a technological additive in several functional groups, including the functional group of substances for reduction of the contamination of feed by mycotoxins for use in feed for ruminants, poultry and pigs (1m558).[3] Moreover, the additive is currently authorised as a binder, anti-caking agent and a substance for control of radionuclide contamination for all animal species (1m558i).

The FEEDAP Panel has adopted several opinions on safety and efficacy of bentonite when used in feed for all animal species (EFSA FEEDAP Panel, 2011a, 2011b, 2012, 2013, 2017).

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 bentonite as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 14 June 2023 to 14 September 2023 for which the received comments 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, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 19 January to 9 February 2024 for which no comments were received.

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.

[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]Biomin GmbH, Erber Campus 1, 3131 Getzersdorf, Austria.
[3]Commission Implementing Regulation (EU) No 1060/2013 of 29 October 2013 concerning the authorisation of bentonite as a feed additive for all animal species. OJ L 289, 31.10.2013, p. 33.
[4]Dossier reference: FEED-2022-10750.
[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, p. 1–48.
[6]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

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 bentonite in animal feed are valid and applicable for the current application.[7]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of bentonite is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3 | ASSESSMENT

Bentonite is currently authorised as a technological additive (functional group: substances for reduction of the contamination of feed by mycotoxins: aflatoxin B1) when used in feed for ruminants, poultry and pigs. The present application regards the renewal of this authorisation.

3.1 | Characterisation

3.1.1 | Characterisation of the additive

The present authorisation sets a specification for bentonite to contain ≥ 70% of smectite (dioctaedral montmorillonite), less than 10% of opal and feldspar and less than 4% of quartz (crystalline silica) and calcite and an aflatoxin B1 binding capacity above 90%.[9]

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

The mineralogical composition of the additive was analysed by x-ray powder diffraction (XRPD) on five production batches of the additive. The results confirmed compliance with the specifications in terms of smectite (Table 1).[11] The FEEDAP Panel notes that opal is not present in the additive and that feldspar was slightly above the specifications in all the batches analysed.[12]

The grain size analysis was performed in five batches of the additive, by a combination of wet sieving (for fraction over 20 μm) and automatic sedimentation analysis (for fraction below 20 μm). The results showed that the fraction below 20 μm consisted in 77.5% of clay (range: 76%–81%), 19.2% of slit (range: 15.8%–21.5%) and 2.2% of sand (2.5%–3.8%). The clay fraction below 2 μm was composed solely of smectite (no other clay mineral was present), as analysed with XRD.

TABLE 1 Mineralogical composition of bentonite (measured in five batches).

Mineral component	Average (%)	Range (%)
Smectite	78.6	76.9–80.6
Quartz	0.8	0.6–0.9
Feldspar	10.9	10.6–11.1
Plagioclase	5.4	4.5–6.0
Calcite	1.0	0.6–1.3
Apatite	1.2	1.1–1.2
Anatase	0.6	0.5–0.9
Mica	0.5	0.3–0.7
Illite	1.3	0.6–2.3

[7]Evaluation report available on the EU Science Hub: https://joint-research-centre.ec.europa.eu/reports-and-technical-documentation/fad-2016-0051_en.

[8]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. 12173–10-3.

[9]Regulation (EU) No 1060/2013 of 29 October 2013 concerning the authorisation of bentonite as a feed additive for all animal species, OJ L 289, 31.10.2013, p. 33–37.

[10]2_1 and 2_2 Sect_II.

[11]Annex II_02.

[12]The Panel notes that although the levels of feldspar in the authorising regulation are set < 10%, the data provided in the present dossier are in line with the data assessed in the dossier on which the original authorisation was based (FAD-2010-0018).

The chemical composition of five production batches of the additive was analysed with X-ray fluorescence (XRF)[13] and it is reported in Table 2.

TABLE 2 Average chemical composition (expressed as % oxide) of five batches of the additive.

Chemical compound	%	Chemical compound	%
SiO_2	58.0	MgO	2.1
Al_2O_3	19.0	Na_2O	1.1
Fe_2O_3	6.2	TiO_2	0.8
CaO	3.1	P_2O_5	0.4
K_2O	2.4	Mn_3O_4	0.1

Three of the above five batches of the additive were analysed for cadmium (Cd), fluorine (F), lead (Pb), mercury (Hg) and arsenic (As).[14] The average values and ranges were: 0.09 mg Cd/kg (0.08–0.09 mg/kg), 6.16 mg F/kg (5.59–6.52 mg/kg), 22.5 mg Pb/kg (21.1–22.8 mg/kg) and 2.16 mg As/kg (1.66–2.56 mg/kg), while the levels of Hg were below the limit of quantification (LOQ) of the analytical method.[15] Three additional batches of the additive were analysed for nickel, showing an average value of 2.42 mg/kg (2.33–2.47 mg/kg).[16]

Polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (DL-PCBs) were analysed in three batches. All values were below the corresponding LOQ. The calculated upper bound concentration was 0.062 ng WHO-PCDD/F -TEQ/kg for the sum of PCDD/Fs, and 0.12 ng WHO-PCDD/F-PCB-TEQ/kg for the sum of PCDD/Fs and DL-PCBs (all values are expressed based on 88% dry matter).[17]

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns.

The average aflatoxin B1 (AfB1) binding capacity, measured in five batches of the additive, was 98%, thus complying with the specifications in the current authorisation (AfB1 binding capacity > 90%).[18]

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

The capacity of the additive to interfere with the analytical determination of mycotoxins was studied for three batches of the additive in feed contaminated with aflatoxin B1, B2, G1 and G2. Each aflatoxin was introduced at the concentration of approximately 5 µg/kg, in the absence or presence of 3 g bentonite per kg of feed. The presence of the additive in the feed did not significantly influence the recovery of aflatoxins. Based on these results, bentonite does not interfere with analysis of aflatoxins in the studied feed.[19]

3.1.3 | Physico-chemical properties of the additive

Since no changes were introduced in the additive manufacturing process, the data described in the previous opinion with regards to the physico-chemical properties still apply (EFSA FEEDAP Panel, 2011a, 2011b).

Additionally, the particle size distribution of three new batches of the additive was evaluated by laser diffraction.[20] The results, reported based on the volume distributions, showed that around 90% of the particles were below 107 µm, 50% were below 31 µm and 10% were below 4.9 µm. The additive was also analysed with scanning electron microscopy (SEM). The results showed a wide range of particle sizes present, from sub-micron to approximately 30 µm, with occasional larger particles. A subsequent filtration study and nanoparticle tracking analysis indicated the presence of a significant number-based fraction of small particles.

[13]Annex II_02D.

[14]Annex II_04.

[15]LOQ for mercury 0.05 mg/kg.

[16]Annex II_04A, Annex II_04B and Annex II_04C.

[17]Annex II_05. Upper bound concentrations are 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 PCDD/Fs and DL-PCBs established by WHO in 2005 (van den Berg et al., 2006).

[18]Annex II_03.

[19]Annex II_27A.

[20]Annex II_06A.

3.1.4 | Conditions of use

The additive is currently authorised for use in feedingstuffs for ruminants, poultry and pigs, with a maximum content of 20,000 mg/kg of complete feed.

Under other provisions of the authorisation, it is stated:

1. Indicate in the instructions for use:
    a. 'The simultaneous oral use with macrolides shall be avoided';
    b. For poultry: 'The simultaneous use with robenidine shall be avoided'.
2. For poultry: the simultaneous use with coccidiostats other than robenidine is contraindicated with level of bentonite above 5000 mg/kg of complete feed.
3. The total amount of bentonite must not exceed the permitted maximum level in complete feedingstuff of 20,000 mg/kg of complete feedingstuff.
4. The use of the additive is allowed in feedingstuffs complying with the European Union legislation on undesirable substances in animal feed.
5. For safety: breathing protection, glasses and gloves shall be used during handling.

The applicant did not request any change in the current conditions of the authorisation.[21]

3.2 | Safety

The safety of bentonite for the target species, consumers, users and the environment was evaluated in a previous opinion (EFSA FEEDAP Panel, 2011a, 2011b). The FEEDAP Panel considered 'as a conservative estimate 0.5% bentonite to be safe for all target animal species'. The additive was also considered safe for consumers and the environment. Bentonite was not considered an irritant to skin but was considered a mild eye irritant. Moreover, bentonite-airborne dust was associated with elevated susceptibility to pulmonary infections.

The applicant states that no incidents or safety issues have been documented or reported since the previous authorisation.[22]

The applicant provided a literature search on the safety of bentonite for the target animals, consumers, users and the environment (Section 3.2.2) and data on the genotoxic potential of the additive (Section 3.2.1).

3.2.1 | Genotoxicity studies

3.2.1.1 | *Bacterial reverse mutation test*

In order to investigate the potential of bentonite to induce gene mutations in bacteria, an Ames test was performed in Salmonella Typhimurium strains TA1535, TA1537, TA98, TA100 and in *Escherichia coli* strain WP2uvrA(pKM101), both in the presence and absence of metabolic activation.[23] The study was performed according to the OECD Test Guideline 471 (1997) and was claimed to be compliant with the principles of Good Laboratory Practice (GLP). The test item was insoluble in water. Five concentrations of a suspension obtained in NaCl 0.15 M from bentonite (range from 50 to 5000 μg/plate) were tested in two independent experiments applying the plate incorporation and pre-incubation methods. No toxicity was observed in any experimental condition. Precipitate not interfering with the analysis was observed at the two highest concentrations tested (1500 and 5000 μg/plate) in all the experimental conditions. No significant changes in the number of revertant colonies were induced by the test item compared to the vehicle controls at any concentration and with any tested strain. 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 bentonite to induce chromosomal damage, an in vitro micronucleus assay was performed in Chinese Hamster Ovary (CHO) cells according to the OECD Test Guideline 487 (2023), in a study claimed to be compliant with the principles of GLP.[24] The test item was insoluble in water and a suspension was obtained in NaCl 0.15 M by continuous stirring. Based on the results of a preliminary cytotoxicity test, three concentrations of the suspension were selected for the analysis of the frequency of micronuclei applying a short treatment (4 h + a recovery period 1.5–2 times the cell

[21] 2_5 Sect_II.
[22] Annex III_01.
[23] Annex III_03.
[24] Annex III_04.

cycle) in the absence (51.2, 89.6, 128 μg/mL) and presence (128, 224, 320 μg/mL) of metabolic activation and a continuous treatment (1.5–2 times the cell cycle) (35.84, 51.2, 89.6 μg/mL) in the absence of metabolic activation. No cytotoxicity was observed after treatment with the test item, as measured by the Relative Increase in Cell Count. No increase in the frequency of micronuclei was observed in treated cultures compared to vehicle control cultures at any concentration and in any experimental condition. Therefore, the FEEDAP Panel concludes that the soluble part of the test item, if any, does not induce structural and numerical chromosome aberrations under the experimental conditions employed in the study.

3.2.1.3 | *Conclusion on genotoxicity*

Based on the results of the available studies, the FEEDAP Panel concludes that the additive under assessment does not raise concern for genotoxicity.

3.2.2 | Extensive literature search

The applicant performed an extensive literature search (ELS) to support that the additive remains safe under the approved conditions for the target animals, consumers, users and the environment.[25] The search covered the period 2011–2021 and the following databases were used: PubMed, Scopus, Google Scholar and SciFinder-n. The search protocol described the inclusion and exclusion criteria applied for the screening process. In total 637 articles were considered for the screening and after applying the exclusion criteria, a total of 72 publications were retrieved and considered eligible by the applicant for the safety for the target species and these are assessed below (Section 3.2.3). No relevant papers were found on the safety for the consumers, users and the environment.

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

A total of 72 publications were retrieved and considered eligible by the applicant for the safety for the target species. No relevant papers were identified regarding the safety for the consumers or the environment.

The Panel noted that in none of the publications identified bentonite was supplemented to feed alone, but in commercial products combined with other additives, and in all cases at levels below the maximum authorised one. Only one (Majewska et al., 2011), out of the 72 publications screened, showed an adverse effect on the feed-to-gain ratio of the chickens for fattening, when the diets were supplemented with 0.1% of a product containing bentonite, compared with a control group, the diets of both groups containing levels of mycotoxins within the legal limits or recommendations. However, it is worth noting that the specific bentonite content in the test item used in the study was not specified, [redacted].[26] The Panel notes that in 19 publications submitted, positive or no effect of the dietary supplementation of products containing bentonite at similar levels [redacted] were observed in chickens for fattening. Based on all the data provided, the Panel concludes that, in light of the current knowledge, there is no novel information that would contradict the previous conclusions.

Therefore, considering the above and the fact that the manufacturing of the additive, specifications and conditions of use have not been modified, the FEEDAP Panel concludes that bentonite remains safe for the target species, the consumer 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 the additive is non-irritant/non-corrosive to skin and a mild irritant to eyes (EFSA FEEDAP Panel, 2011a, 2011b).

No new information regarding the safety for the user was submitted for the current application, and no relevant papers were identified in the ELS.

Based on the highest dusting potential measured (6740 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 (2.33–2.47 mg Ni/kg). The European Directive 2022/431[27] sets 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 FEEDAP Panel notes that the additive contains crystalline silica (0.6%–0.9%). Inhalation of crystalline silica is known to be hazardous and is associated with increased risk of lung cancer and the industrial disease, silicosis. The European

[25] Annex III_02A.

[26] Answer_Q1_adAnnexIII_02A.

[27] DIRECTIVE (EU) 2022/431 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ L 88/2, 16.3.2022, 14 pp.

Directive 2017/2398[28] sets an OEL of 0.1 mg/m^3 of air for respirable crystalline silica dust. Therefore, to reduce the risk, the FEEDAP Panel considers that the exposure of the users should be minimised.

Considering the content of nickel, the additive should be considered a skin and respiratory sensitiser.

Considering the above, the Panel concludes that bentonite is not irritant to the skin but is irritant to the eyes and should be considered a skin and respiratory sensitiser. Any exposure is considered a risk.

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

The Panel concludes that bentonite remains safe for ruminants, poultry and pigs, consumers and the environment under the authorised conditions of use. Regarding user safety, the additive is not irritant to the skin but is irritant to the eyes and should be considered a skin and respiratory sensitiser. Any exposure is considered a risk.

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

5 | RECOMMENDATION

The FEEDAP Panel recommends updating the specifications of feldspar to reflect the analysed values.

ABBREVIATIONS

CHO	Chinese Hamster Ovary
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 Practice
LOQ	limit of quantification
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
SEM	scanning electron microscopy
WHO	World Health Organization
XRF	x-ray fluorescence
XRPD	x-ray powder diffraction

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[28]Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ L 345, 27.12.2017, 8 pp.

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