CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance kieselgur (diatomaceous earth)

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State Austria and co-rapporteur Member State Greece for the pesticide active substance kieselgur (diatomaceous earth) and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of kieselgur (diatomaceous earth) as an insecticide and acaricide on stored cereals, empty storage rooms and storage rooms, mills and warehouses (with stored goods). The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed.

Keywords: kieselgur, diatomaceous earth, peer review, risk assessment, pesticide, insecticide and acaricide

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Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Kieselgur (diatomaceous earth) is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Austria, and co-rapporteur Member State (co-RMS), Greece, received an application from Biofa AG for the renewal of approval of the active substance kieselgur. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005.

An initial evaluation of the dossier on kieselgur was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by the European Food Safety Authority (EFSA) in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of kieselgur according to the representative uses as an insecticide and acaricide on stored cereals, empty storage rooms and storage rooms with stored goods, as proposed at the European Union (EU) level, result in a sufficient insecticidal and acaricidal efficacy against the target organisms.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of kieselgur or the representative formulations.

There are no critical areas of concern identified in the mammalian toxicology area if operator exposure is compared with a refined acceptable operator exposure concentration (AOEC) that is derived with a reduced uncertainty factor taking into consideration the specificity of kieselgur, i.e. concerns limited to local effects in the lungs upon repeated exposure through inhalation and specific use in stored cereals and storage rooms where bystanders and residents are not exposed. However, even with this refinement, estimated operator exposure exceeds the AOEC for two of the four representative uses.

No risk to consumer via intake is expected from the representative uses of the kieselgur on stored cereals and empty storage rooms. This assessment covers the most critical authorised uses on stored cereals and empty storage from European Member States. Due to the nature of kieselgur, no maximum residue levels (MRLs) are needed and EFSA recommends its inclusion in the Annex IV of Regulation (EC) No 396/2005.

An MRL application for inclusion of kieselgur into Annex IV of Regulation (EC) No 396/2005 has also been submitted.

Environmental exposure is not expected for the indoor uses of kieselgur.

A low risk to birds, wild mammals, aquatic organisms, bees, non-target arthropods other than bees, earthworms, soil organisms, non-target terrestrial plants and sewage treatment organisms is concluded for all the representative uses.

Kieselgur does not meet the criteria for endocrine disruption for humans and non-target organisms through estrogen, androgen, thyroid, steroidogenic (EATS) modalities as set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

Table of contents

Background

Commission Implementing Regulation (EU) No 844/2012,[1] as amended by Commission Implementing Regulation (EU) No 2018/1659[2] (hereinafter referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009.[3] This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS Austria and co-RMS Greece received an application from Biofa AG for the renewal of approval of the active substance kieselgur (diatomaceous earth). In addition, Biofa AG submitted an application to include the substance into Annex IV of Regulation (EC) No 396/2005.[4] Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Greece), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on kieselgur in the RAR, which was received by EFSA on 22 February 2019 (Austria, 2019a). Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 19 August 2019, EFSA invited the Member States to submit their Good Agricultural Practices (GAPs) that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Biofa AG, for consultation and comments on 29 March 2019. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 29 May 2019. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicants' response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 15 July 2019. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the area of mammalian toxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

[2] Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

[3] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the Article 12 MRL review of Regulation (EC) No 396/2005, took place with Member States via a written procedure in January-February 2020.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of kieselgur as an insecticide and acaricide on stored cereals, empty storage rooms and storage rooms, mills and warehouses (with stored goods), as proposed by the applicant. In accordance with Article 12 (2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2020), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (15 July 2019);
- the evaluation table (14 February 2020);
- the report of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Austria, 2019b), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Kieselgur (diatomaceous earth) is considered by the International Organization for Standardization not to require a common name. It consists mainly of silicon dioxide (IUPAC).

The representative formulated product for the evaluation was 'SilicoSec', a contact powder (CP), containing 1,000 g/kg kieselgur.

The representative uses evaluated comprise applications by mixing with stored cereal grain during putting into storage and by dusting in empty storage rooms and storage rooms with stored cereals, as insecticide/acaricide, for the control of insects and mites. Full details of the GAP can be found in the list of end points in Appendix A.

Data were submitted to conclude that the representative uses of kieselgur proposed at EU level result in a sufficient insecticidal and acaricidal efficacy against the target organisms, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014)

A data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: European Commission, 2000a,b.

It should be noted that the active substance is constituted of mined diatomaceous earth. The active substance kieselgur consists of 1,000 g/kg diatomaceous earth with a minimum content of amorphous silica of 800 g/kg. Crystalline silica with diameter below 10 μm was defined as relevant impurity with a maximum limit of 1 g/kg. FAO specification does not exist. Considering the changes in the expression of the purity and the changes in the relevant impurity definition, it is proposed to update the reference specification.

The available data regarding the identity of kieselgur and its physical and chemical properties are given in Appendix A. Appropriate analytical methods exist for the determination of the composition of the technical product and the identical formulation. Crystalline silica in kieselgur technical and formulation can be determined by X-ray diffraction analysis.

The need for methods of analysis for monitoring this compound in food of plant and animal origin, in the environment and in body fluids and tissues has been waived due to the nature of the compound. Inductively coupled plasma optical emission spectroscopy (ICP-OES) and NIOSH X-ray diffraction method can be used for the determination of the crystalline silicon dioxide in the air.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: European Commission, 2003, 2012, EFSA PPR Panel, 2012 and ECHA, 2017.

Kieselgur was discussed during the Pesticides Peer Review Experts' Meeting 18 in November 2019.

One relevant impurity, crystalline silica with diameter below 10 μm, is considered a human carcinogen by inhalation, self-classified (classification proposed by registrants) as Carc. 1A (H350 'May cause cancer by inhalation' according to Regulation (EC) No 1272/2008[5]) and needs to remain below 1 g/kg.

Considering the intrinsic physico-chemical properties of kieselgur (insoluble and inert), the rate and extension of oral absorption is considered to be negligible and no metabolism is expected to occur. In addition, no adverse effects were observed upon oral administration (see below). On this basis, the submission of additional toxicological studies performed by the oral route was waived, such as toxicokinetic studies, long-term toxicity, carcinogenicity or reproductive toxicity.

Acute toxicity studies were submitted confirming the low toxicity of the substance when administered by the oral or inhalation routes. No potential for skin or eye irritation was observed. No genotoxic potential on lung and stomach cells was seen in an intratracheal Comet assay performed with kieselgur in rats.

With regard to short term toxicity, kieselgur was tested in a 90-day oral toxicity study in rats, where no adverse effects were observed at dose levels exceeding 4,000 mg/kg body weight (bw) per day. In a 28-day study by inhalation, kieselgur administration of 5 mg diatomaceous earth/m^3 per six hours/day resulted in adverse local effects characterised by increased lung weight, accumulation of macrophages and changes in macrophage and neutrophil counts in the bronchoalveolar lavage (BAL) fluid. The respective no-observed adverse effect concentration (NOAEC) was identified at 1 mg/m^3. Additional short-term toxicity studies by inhalation, reproductive and developmental toxicity studies by the oral route were provided for similar substances (silica (aero)gel, synthetic amorphous silica, fumed hydrophobic silica) showing a similar toxicity profile as kieselgur, i.e. no adverse effects were observed after oral administration, while similar inflammatory lung responses were induced by inhalation. These studies were considered supplementary information since uncertainties were identified to allow read across between the different silica derivatives due to their different physico-chemical properties.

Since no concern was identified if kieselgur is administered by the oral route, the same lack of toxicity is expected through dermal exposure taking into consideration the insoluble and inert properties of the active substance.

[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

Toxicological reference values related to oral exposure were not considered necessary, i.e. acceptable daily intake (ADI), acute reference dose (ARfD) or (acute) acceptable operator exposure level (AAOEL/AOEL), and were not established. It was, however, agreed that, considering the toxicity profile of the substance by inhalation, an acceptable operator exposure concentration (AOEC) was needed to perform a non-dietary risk assessment related to inhalation exposure. These conclusions are in agreement with the previous conclusion of the peer review (EFSA, 2012).

Taking into consideration the minimum safety margin of 100 according to point 3.6.1 of Annex II to Regulation (EC) No 1107/2009, the AOEC should be 0.01 mg/m^3 based on the NOAEC of 1 mg/m^3 from the 28-day toxicity study by inhalation in rats. This conclusion is in agreement with the conclusion reached under the confirmatory data procedure (EFSA, 2016). The experts considered however that this uncertainty factor does not reflect the specificity of kieselgur, i.e. concerns only upon repeated exposure by inhalation and specific indoor uses where bystanders and residents are not exposed – and agreed that an overall reduced uncertainty factor of 12.5 is more appropriate, 5 to account for intraspecies variability (because only professionals are exposed and not more sensitive groups included in residents and bystanders[6]) and 2.5 for interspecies variability in toxicodynamics (toxicokinetic not being relevant for local effects in the lungs). The resulting refined AOEC is 0.06 mg/m^3 based on the same 28-day subacute toxicity study in rats normalised for 8 hours exposure as the NOAEC is derived from 6 hours inhalation exposure study.[7] It is noted that the basis of this conclusion is in line with the short-term reference value established by the biocides review, the difference between the two values being due to the population covered (the biocide value is protective of the general population while the AOEC value agreed as plant protection product is applicable to professional users, relevant to the representative use only), i.e. short-term acceptable exposure concentration (AECshort-term) of 0.03 mg/m^3 per day.[8] This timeframe was considered to cover the representative uses. No acute AOEC was established as it was not needed.

Kieselgur is proposed to be used in stored cereals, empty storage rooms or storage rooms, mills and warehouses with stored goods. The EFSA calculator does not cover this type of applications and non-dietary exposure was calculated according to the Technical Notes for Guidance (TNsG) for biocides[9] which is based on the same set of exposure data also used for the German model and use the same breathing rate of 1.25 m^3/h for operators as recommended in the EFSA guidance (EFSA, 2014). For the use in stored cereals (mixing with grains), the operator exposure estimates are above the AOEC of 0.01 mg/m^3, even when personal protective equipment (PPE) such as respiratory protective equipment (RPE) is used. When compared with the refined AOEC of 0.06 mg/m^3, the use of respiratory protective equipment is sufficient to ensure that the AOEC is not exceeded. Worker exposure by inhalation was considered negligible for this use since the product remains as a solid coating on the treated cereals. Bystander and resident's exposures were considered not relevant.

Regarding uses in empty storage rooms or storage rooms, mills and warehouses (with stored goods), estimated exposure always exceeded the AOEC, either of 0.01 or 0.06 mg/m^3, even when operators wear RPE. For these uses, worker exposure was not considered relevant because re-entry is not necessary shortly after spraying. As for the previous uses, bystander and resident's exposure are not considered relevant.

3. Residues

Kieselgur occurs naturally and toxicologically is considered not relevant for the consumer since the setting of reference values (ADI, ARfD) were not necessary (see Section 2). No risk consumer via dietary intake is expected as the relevant impurity of kieselgur (crystalline silica) is classified as carcinogenic by inhalation. Due to the inert and insoluble properties, kieselgur is not expected to degrade or to form other metabolites relevant for the consumer when used as plant protection product.

[6] European Chemicals Agency (ECHA) 2012. Guidance on information requirements and chemical safety assessment, Chapter R.8: Characterisation of dose [concentration]-response for human health under REACH ECHA-2010-G-19-EN, November 2012.

[7] See experts' consultation 2.2 (Report Pesticides Peer Review Experts' Meeting 18 in Mammalian Toxicology (November 2019) (EFSA, 2020).

[8] Assessment Report Silicon dioxide Kieselguhr, Product-type 18 (insecticides, acaricides and products to control other arthropods) according to Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Evaluation of active substances, November 2016, France.

[9] Human Exposure to biocidal products, Technical Notes for Guidance (TNsG) under the Biocide Product Directive 98/8/EC, June 2007 available on https://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg-human-exposure-2007_en.pdf.

The review of existing maximum residue levels (MRLs) under Article 12 of Regulation (EC) No 396/2005 is covered by the assessment of the representative uses on stored cereals and empty storage rooms since the most critical authorised uses from the European Member States are similar. EFSA recommends the inclusion of kieselgur in the Annex IV of Regulation (EC) No 396/2005 and no MRLs are necessary for this active substance.

4. Environmental fate and behaviour

Due to the nature of the substance and the uses in closed environments (silos, mills, empty rooms), the exposure of kieselgur to soil, water and air is not expected.

5. Ecotoxicology

Given that environmental exposure is not expected from the indoor uses of kieselgur, a low risk is concluded to birds, wild mammals, aquatic organisms, bees, non-target arthropods other than bees, earthworms, soil organisms, non-target terrestrial plants and sewage treatment organisms. This conclusion applies to all representative uses.

6. Endocrine disruption properties

The assessment of the endocrine disruption potential of kieselgur was conducted in accordance with ECHA/EFSA guidance (2018).

Kieselgur has a non-toxic mode of action and is non-toxic by itself by the oral route. Although no (eco)toxicological data are available to assess the endocrine disrupting properties of kieselgur for **humans** and **non-target organisms**, this does not appear scientifically necessary considering the nature of the substance, being insoluble and inert. Therefore, it is considered scientifically justified to waive the assessment of endocrine disrupting properties of this substance both for humans and non-target organisms.

Considering the above, it can be concluded that kieselgur does not meet the criteria for endocrine disruption through EATS modalities for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605[10].

7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Kieselgur	Not applicable for a mineral. Assumed to be stable	Low risk to soil organisms

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[(a)]	Pesticidal activity	Toxicological relevance
Kieselgur	Not relevant as it is a mineral component of soil	Not applicable	Yes	Not applicable

(a): FOCUS scenarios or a relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Kieselgur	Low risk to aquatic organisms

[10] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

Table 4: Air

Compound (name and/or code)	Toxicology
Kieselgur	Rat LC_{50} inhalation > 25 g/m^3 air/1 h (whole body) (supplementary information) – classification criteria would not be met (currently there is no harmonised classification) 28-day toxicity by inhalation NOAEC: 1 mg/m^3

LC_{50}: lethal concentration, median; NOAEC: no observed adverse effect concentration.

8. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- A search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011; relevant for all representative uses evaluated, see sections 2[11] and 5[12]).

9. Particular conditions proposed to be taken into account to manage the risk(s) identified

- Operators exposed to kieselgur in stored cereals (mixing it with grains) need to use RPE to ensure that the refined AOEC of 0.06 mg/m^3 (taking into consideration a reduced uncertainty factor due to the specificity of kieselgur, i.e. concerns limited to local effects in the lungs upon repeated exposure through inhalation and specific use in stored cereals and storage rooms) is not exceeded (see Section 2).

10. Concerns

10.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[13] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

No issues that could not be finalised have been identified.

10.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

[11] See evaluation table, section 2, data requirement 2.8.
[12] See evaluation table, section 5, data requirement 5.1.
[13] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

No critical areas of concern have been identified.

10.3. Overview of the concerns identified for each representative use considered (Table 5)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 9, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

Table 5: Overview of concerns

Representative use		Stored cereals (application at danger of infestation)	Stored cereals (application at infestation)	Empty storage rooms	Storage rooms, mills and warehouses (with stored goods)
Operator risk	Risk identified	X[(b)]	X[(b)]	X[(c)]	X[(c)]
	Assessment not finalised				
Worker risk	Risk identified				
	Assessment not finalised				
Resident/ bystander risk	Risk identified				
	Assessment not finalised				
Consumer risk	Risk identified				
	Assessment not finalised				
Risk to wild non-target terrestrial vertebrates	Risk identified				
	Assessment not finalised				
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified				
	Assessment not finalised				
Risk to aquatic organisms	Risk identified				
	Assessment not finalised				
Groundwater exposure to active substance	Legal parametric value breached				
	Assessment not finalised				
Groundwater exposure to metabolites	Legal parametric value breached				
	Parametric value of 10 μg/L[(a)] breached				
	Assessment not finalised				

The superscript numbers relate to the numbered points indicated in Sections 10.1 and 10.2. Where there is no superscript number, see Sections 2–6 for further information.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.

(b): only when exposure is compared to the AOEC of 0.01 mg/m^3, calculated with the minimum safety margin of 100 according to point 3.6.1 of Annex II to Regulation (EC) No 1107/2009.

(c): when exposure is compared either to the AOEC of 0.01 mg/m^3 (calculated with the minimum safety margin of 100 according to point 3.6.1 of Annex II to Regulation (EC) No 1107/2009) or to the refined AOEC of 0.06 mg/m^3 (taking into consideration a reduced uncertainty factor due to the specificity of kieselgur, i.e. concerns limited to local effects in the lungs upon repeated exposure through inhalation and specific use in stored cereals and storage rooms where bystanders and residents are not exposed).

References

Austria, 2019a. Renewal Assessment Report (RAR) on the active substance kieselgur prepared by the rapporteur Member State Austria, in the framework of Commission Implementing Regulation (EU) No 844/2012, February 2019. Available online: www.efsa.europa.eu

Austria, 2019b. Revised Renewal Assessment Report (RAR) on kieselgur prepared by the rapporteur Member State Austria in the framework of Commission Implementing Regulation (EU) No 844/2012, November 2019. Available online: www.efsa.europa.eu

ECHA (European Chemicals Agency), 2017. Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. Version 5.0, July 2017. Reference: ECHA-17-G-21-EN; ISBN: 978-92-9020-050-5; available online: https://echa.europa.eu/guidance-documents/guidance-on-clp

ECHA and EFSA (European Chemicals Agency and European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311,135 pp. https://doi.org/10.2903/j.efsa.2018.5311. ECHA-18-G-01-EN

EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092, 49 pp. https://doi.org/10.2903/j.efsa.2011.2092

EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance kieselgur (diatomaceous earth). EFSA Journal 2012;10(7):2797, 35 pp. https://doi.org/10.2903/j.efsa.2012.2797. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp. https://doi.org/10.2903/j.efsa.2014.3874. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for kieselgur (diatomaceous earth) in light of confirmatory data. EFSA supporting publication 2016:EN-1064. 11 pp.

EFSA (European Food Safety Authority), 2020. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance kieselgur. Available online: www.efsa.europa.eu

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2012. Guidance on dermal absorption. EFSA Journal 2012;10(4):2665, 30 pp. https://doi.org/10.2903/j.efsa.2012.2665

European Commission, 2000a. Residues: guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3029/99-rev. 4, 11 July 2000

European Commission, 2000b. Technical material and preparations: guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3030/99-rev. 4, 11 July 2000

European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003

European Commission, 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. SANCO/10597/2003-rev. 10.1, 13 July 2012.

European Commission, 2014. Guidance document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012. SANCO/2012/11251-rev. 4, 12 December 2014.

Abbreviations

AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEC	acceptable operator exposure concentration
AOEL	acceptable operator exposure level
ARfD	acute reference dose
BAL	bronchoalveolar lavage
bw	body weight
DAR	draft assessment report
EATS	estrogen, androgen, thyroid, steroidogenic
ECHA	European Chemicals Agency
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice

ICP-OES	inductively coupled plasma optical emission spectroscopy
IUPAC	International Union of Pure and Applied Chemistry
LC_{50}	lethal concentration, median
MRL	maximum residue level
NOAEC	no observed adverse effect concentration
PPE	personal protective equipment
RAR	Renewal Assessment Report
RMS	rapporteur Member State
RPE	respiratory protective equipment
TNsG	technical notes of guidance (biocides)

Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2020.6054