CONCLUSION ON PESTICIDES PEER REVIEW

efsa JOURNAL

APPROVED: 21 December 2022

doi: 10.2903/j.efsa.2023.7805

Peer review of the pesticide risk assessment of the active substance sulfur

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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 France and co-rapporteur Member State Slovenia for the pesticide active substance sulfur 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 sulfur as a fungicide and acaricide on grapevine and cereals (wheat, barley, oat, rye, triticale). 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. Concerns are reported where identified.

Keywords: sulfur, peer review, risk assessment, pesticide, fungicide, MRL review

Requestor: European Commission

Question number: EFSA-Q-2017-00275

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Note/Update: This scientific output, approved on 21 December 2022, supersedes the previous output published on 6 April 2009 (EFSA, 2009).

Declarations 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.

Acknowledgements: EFSA wishes to thank the rapporteur Member State France for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Alvarez F, Arena M, Auteri D, Binaglia M, Castoldi AF, Chiusolo A, Colagiorgi A, Colas M, Crivellente F, De Lentdecker C, De Magistris I, Egsmose M, Fait G, Ferilli F, Gouliarmou V, Nogareda LH, Ippolito A, Istace F, Jarrah S, Kardassi D, Kienzler A, Lanzoni A, Lava R, Leuschner R, Linguadoca A, Lythgo C, Magrans O, Mangas I, Miron I, Molnar T, Padovani L, Panzarea M, Parra Morte JM, Rizzuto S, Serafimova R, Sharp R, Szentes C, Szoradi A, Terron A, Theobald A, Tiramani M, Vianello G and Villamar-Bouza L, 2023. Conclusion on the peer review of the pesticide risk assessment of the active substance sulfur. EFSA Journal 2023;21 (3):7805, 25 pp. https://doi.org/10.2903/j.efsa.2023.7805

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

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. Sulfur 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), France, and co-rapporteur Member State (co-RMS), Slovenia, received an application from the Sulfur Working Group (SWG) (BASF SE, Syngenta Crop Protection AG, Agrostulln GmbH, UPL Europe Limited) and from the Sulphur Task Force (STF) (Azufrera y Fertilizantes Pallarés, S.A. (AFEPASA), CEPSA QUÍMICA S.A, CIECH Sarzyna S.A., Julio Cabrero y Cía, S.L., Petróleos de Portugal (now Petrogal, S.A.), Quimetal Industrial S.A., Repsol Lubricantes y Especialidades S.A. (now Repsol Lubricants and Specialties, S.A.), SAPEC Agro S.A. (now ASCENZA Agro S.A.), S.T.I. Solfotecnica Italiana S.p.A., Sulphur Mills Ltd., Zolfindustria S.r.l., Zolfital S.p.A.) for the renewal of approval of the active substance sulfur.

An initial evaluation of the dossier on sulfur 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 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 sulfur according to the representative uses as a fungicide and acaricide on grapevine and cereals (wheat, barley, oat, rye, triticale), as proposed at EU level result in a sufficient fungicidal and acaricidal efficacy against the target powdery mildew (*Erysiphe necator* (*Uncinula necator*, *Oidium tuckeri*), *Blumeria graminis (Erysiphe graminis, Oidium monilioides*)), erineum leaf mite (*Colomerus vitis (Eriophyes vitis, Phytoptus vitis*)) and rust mite (*Calepitrimerus vitis (Epitrimerus vitis, Phyllocoptes vitis))*.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to the identity, physical–chemical properties and analytical methods section.

In the area of mammalian toxicology, the short-term inhalation toxicity of sulfur should be addressed in order to conclude on the potential risks from non-dietary exposure via inhalation of the Sulphur Dust product. These data might negate the need for respiratory protective equipment for operators to be used. The available information was sufficient to conclude on all other areas of the mammalian toxicology assessment.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to the residue section. With respect to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 for inclusion in Annex IV of Regulation (EC) No 396/2005 two criteria were considered to remain met for sulfur for the following reasons: Toxicological reference values are not required for sulfur (criterion III) (see Section 2). The natural exposure from natural sulfur compound sources present in food (e.g. as amino acids, proteins, etc.) is higher than the one linked to the uses assessed in this conclusion as plant protection products (criterion IV). The other three criteria (criteria I, II and V) are not fulfilled.

Elemental sulfur occurs abundantly in nature and associated natural compounds are commonly found in all of the three environmental compartments (soil, water and air). The data available on environmental fate and behaviour were sufficient to carry out the required environmental exposure assessments at the EU level for the representative uses assessed.

In the area of ecotoxicology, high risk was concluded for sediment-dwelling aquatic organisms for the metabolite sulfate following the use of Sulphur Dust. High chronic risk was concluded for honey bee adults and larvae for all representative uses. High in-field risk was indicated for non-target arthropods other than bees for all representative uses (critical areas of concern), while a low off-field risk was concluded only with the implementation of risk mitigation measures for all representative uses. High chronic risk was concluded for soil macroorganisms for all representative uses (critical area of concern). A low risk was concluded for birds and mammals, aquatic organisms dwelling in the water column, sediment-dwellers following the uses of Sulfur 80% WG, non-target terrestrial plants, soil microorganisms and organisms involved in biological methods for sewage treatment.

It is unlikely that sulfur meets the criteria for endocrine disruption 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.

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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 France and co-RMS Slovenia received an application from the Sulfur Working Group (SWG) (BASF SE, Syngenta Crop Protection AG, Agrostulln GmbH, UPL Europe Limited) and from the Sulphur Task Force (STF) (Azufrera y Fertilizantes Pallarés, S.A. (AFEPASA), CEPSA QUÍMICA S.A, CIECH Sarzyna S.A., Julio Cabrero y Cía, S.L., Petróleos de Portugal (now Petrogal, S.A.), Quimetal Industrial S.A., Repsol Lubricantes y Especialidades S.A. (now Repsol Lubricants and Specialties, S.A.), SAPEC Agro S.A. (now ASCENZA Agro S.A.), S.T.I. Solfotecnica Italiana S.p.A., Sulphur Mills Ltd., Zolfindustria S.r.l., Zolfital S.p.A.) for the renewal of approval of the active substance sulfur. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant(s), the co-RMS (Slovenia), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on sulfur in the RAR, which was received by EFSA on 28 September 2020 (France, 2010).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, the Sulfur Working Group (SWG) and the Sulphur Task Force (STF), for consultation and comments on 5 July 2021. 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 7 September 2021. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicants were invited to respond to the comments received. 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 applicants in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS on 11 November 2021. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

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, pp. 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, pp. 1–50.

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 the proposal for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 took place with Member States via a written procedure in November 2022.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulations, evaluated on the basis of the representative uses of sulfur as a fungicide/acaricide on grapevine and cereals (wheat, barley, oat, rye, triticale) as proposed by the applicants. 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 formulations is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for sulfur according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2022), 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 (18 November 2021);
- the evaluation table (19 December 2022);
- the reports of the scientific consultation with Member State experts;
- the comments received on the assessment of the additional information;
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (France, 2022), 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 and its background documents would not be accepted to support any registration outside the 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

The International Organization for Standardization does not require a common name for sulfur (IUPAC).

The representative formulated products for the evaluation were 'Thiovit Jet', 'Microthiol Special Disperss', 'Kumulus WG' and 'Netzschwefel Stulln' all water-dispersible granule (WG) formulations containing 800 g/kg of sulfur, and 'Sulphur Dust' a dustable powder (DP) formulation containing 985 g/kg of sulfur. It is noted that 'Kumulus WG' and 'Netzschwefel Stulln' contain 800 g/Kg as technical sulfur (min. purity 990 g/kg).

The representative uses evaluated for 'Thiovit Jet', 'Microthiol Special Disperss', 'Kumulus WG' and 'Netzschwefel Stulln' comprise foliar spray applications in all EU zones on grapevine, wheat, barley, oat, rye, triticale as fungicide and acaricide. The representative uses evaluated for 'Sulphur Dust' comprise foliar dust applications on grapevine as a fungicide in central and south EU.

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

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, 2000b, 2010, 2012).

A common specification was proposed for all manufacturing sources, and it is based on batch data from industrial scale production. The proposed minimum purity of all the technical materials is 990 g/kg. Mercury, arsenic, cadmium, chromium, lead and nickel were considered new relevant impurities specified at 0.1 mg/kg for mercury, arsenic, chromium and cadmium; at 0.9 mg/kg for lead and at 1.2 mg/kg for nickel. A FAO specification is not available for the active substance. A data gap was identified for Zolfital to provide data on the manufacturing of the technical active substance (see confidential evaluation table for Zolfital and Section 10). The batches used in the toxicological assessment do not support the proposed updated reference specification but do support the current reference specification (see Section 2). The batches used in the ecotoxicological assessment support the proposed updated reference specification and the current reference specification (see Section 5). Since new relevant impurities were defined in comparison to the first approval it is proposed to update the reference specification for sulfur.

The available data regarding the identity of sulfur and its physical and chemical properties have been included in Appendix A.

Adequate methods are available for the generation of data required for the risk assessment. Validation data are missing for the analytical method used in the light stability study of sulfur and its stability against metals; however, it is acknowledged that study results were not used in the risk assessment therefore a data gap was not set. Methods of analysis are available for the determination of the active substance and relevant impurities in the technical materials and in the representative formulations. A data gap was identified for SWG for validated analytical methods with adequate LOQs for the determination of the relevant impurities mercury, arsenic and cadmium in the formulations 'KUMULUS WG' (BASF), 'Thiovit Jet' (Syngenta), 'Netzschwefel Stulln' (Agrostulln) and 'Microthiol Special Disperss' (UPL) (see Section 10). In addition, a data gap was identified for STF to provide validated analytical methods with adequate LOQs for the determination of mercury, arsenic, chromium and cadmium i in the formulation 'Sulphur Dust' (see Section 10). Methods for the analysis of residues in food and feed of plant origin, food of animal origin, body fluids and tissues and environmental compartments are not required as no residue definitions were set. For monitoring sulfur in air an Inductively coupled plasma–optical emission spectrometry (ICP-OES) method was provided, yet significant deficiencies in the method validation, as required according to European Commission, 2010 were observed. However, as a residue definition for sulfur monitoring in air and an A(AOEL) for sulfur was not proposed (see Section 2) a data gap has not been identified.

2. Mammalian toxicity

Sulfur was discussed at the Pesticides Peer Review Experts' Teleconference 85 in July 2022. The following guidance documents were used in the production of this conclusion: European Commission (2003, 2012), EFSA (2014) and ECHA (2017).

Toxicologically relevant impurities, i.e. arsenic (As), cadmium (Cd), chromium (Cr), lead (Pb), mercury (Hg) and nickel (Ni) have been identified in the reference specification. Nevertheless, from a toxicological point of view, their presence is acceptable at the maximum levels proposed of 1.2 mg/kg for Ni, 0.9 mg/kg for Pb, and 0.1 mg/kg for As, Cd, Cr and Hg (which are well below their classification limits according to Regulation (EC) No 1272/2008). It is noted that this has also been confirmed by the RMS using the more conservative approach of ICH Q3D Harmonised Guideline for Elemental Impurities (EMA, 2013). The levels of these impurities were not measured in the toxicological batches. Thus, the test material used in toxicity studies cannot be concluded as fully representative of the proposed reference specification for the active substance and associated impurities (see Section 1; data gap, see Section 10).

The toxicological database for sulfur is limited. Regulatory studies on absorption, distribution, metabolism and excretion (ADME) of sulfur in animals were not available. Information on sulfur ADME was derived from open literature and reviews from regulatory bodies (e.g. EMEA, 2003; EFSA FAF Panel, 2019). The literature search conducted for publications published from 2007 to 2018 did not

identify any relevant data for ADME properties, whereas relevant data, published before 2007 and assessed in the first draft assessment report (DAR) were submitted by the applicants. Based on current knowledge, by oral route elemental sulfur is likely transformed and absorbed as hydrogen sulfide by intestinal mucosa and then oxidised to sulfate. According to published human studies (see EFSA, 2008b) sulfur is well absorbed at low dose levels. Sulfur is uniformly distributed, has no potential for accumulation, and is extensively metabolised to sulfates and sulfides. Sulfates are mainly eliminated in the urine, but at high doses, also via the faeces. Though a comparative *in vitro* metabolism study is not available for sulfur, this has been accepted considering that sulfur is an essential element for all living organisms and that the available ADME data are suggestive of a similar metabolic profile of sulfur after absorption in mammals and humans.

Sulfur has low **acute toxicity** via the oral, dermal and inhalation routes. It has a harmonised classification[4] as Skin irritant Category 2 (ECHA, 2022), whereas the RMS' proposal for sulfur classification for eye irritation was not maintained by ECHA (2022). Sulfur is not sensitising to the skin and not phototoxic in the 3 T3 NRU-Phototoxicity Test; however, due to a peak of absorption in the UVB range, some uncertainty remains as to whether the available *in vitro* phototoxicity test was suitable to detect potential phototoxicity of sulfur in the UVB range (data gap, see Section 10). The RMS did not agree with this data gap.

Oral and dermal **short-term** toxicity studies in rats with sulfur technical and/or 'Sulphur Dust' did not provide any evidence of specific target organ toxicity. The relevant systemic no observed adverse effect levels (NOAELs) were identified at 400 mg/kg body weight (bw) per day for the oral route (body weight and food consumption decrease in a 90-day rat study) and 1,000 mg/kg bw per day for the dermal route (top dose tested in a 28-day rat study). In the rat dermal toxicity study, a local NOAEL of 400 mg/kg bw per day was identified based on hyperkeratosis. Sulfur has not been classified by ECHA (2022) for respiratory irritation after single exposure (STOT SE) following a proposal by the RMS. Reversible signs of respiratory tract irritation (decrease in breathing frequency, irregular and choking breathing) have been found in a rat acute inhalation toxicity study. Irritation of the respiratory tract (cough, upper airway irritation, rhinitis, etc.) has been reported in workers exposed to sulfur. Furthermore, in a recent epidemiological study, residential proximity to elemental sulfur application was associated to increased respiratory symptoms and asthma medication as well as poorer lung function (spirometry measurements) in children living in an agricultural community. A repeat-dose inhalation toxicity study with sulfur was not available, as this is not required for non-volatile active substances. Considering the potential inhalation exposure to sulfur from the application of the 'Sulphur Dust' PPP (application as a very fine powder/dust and inhalation represents the major part of systemic exposure of bystander/resident in an exposure study) and the above-mentioned concerns raised by data on humans following inhalation exposure, the peer review experts agreed to request a short term inhalation toxicity study with sulfur in rodents (data gap, see Section 10) to better address the toxicity of sulfur via this exposure route.

Based on the available *in vitro* and *in vivo* **genotoxicity** data package, the substance is unlikely to be genotoxic. Studies addressing **long-term toxicity/carcinogenesis, reproductive and developmental toxicity, neurotoxicity** or **immunotoxicity** of sulfur are not available. Nonetheless, further data were not required since sulfur is an essential element necessary at high levels and generally regarded as safe for human exposure in view of its low toxicity profile (low acute and short term toxicity, lack of genotoxicity) and high background exposure.

As regards **human data** besides those already mentioned above, there is no evidence of adverse findings except skin, eye and/or respiratory irritation and malaises due to incidental exposure, e.g. in occupational settings. Ingestion of high, non-fatal doses of sulfur can result in metabolic acidosis and intoxication from excessive release of hydrogen sulfide.

Reference values, i.e. acceptable daily intake (**ADI**), (acute) acceptable operator exposure level (**(A)-AOEL**) and acute reference dose (**ARfD**), are considered not needed for sulfur.

In the absence of toxicological reference values for sulfur, **non-dietary exposure** estimates resulting from its use as PPP (based on the EFSA model) were compared with background human exposure levels from the diet and drinking water estimated at 24 mg/kg bw per day, based on data retrieved from a publication of the US National Academy of Medicine (2005).

[4] 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, pp. 1–1355.

For the different sulfur 80% WG formulations, the default **dermal absorption** value of 10% was taken as input value, for both the concentrate and in-use spray dilution. For the 'Sulphur Dust' formulation, based on an *in vitro* study with human skin, the agreed dermal absorption value was set at 1.8%.

Considering the representative uses of the different **sulfur 80% WG formulations**, outdoor on grapevine and cereals, the operator exposure to sulfur is far below – i.e. 2.32% and 1.41%, respectively –the background human exposure level, assuming just the use of standard workwear (without PPE, i.e. gloves) during mixing/loading and application. Exposure to sulfur is estimated to account for 90.4% and 1.49% of human background exposure level respectively for workers re-entering vineyards for hand harvesting, and for workers inspecting and irrigating cereals after application of the different sulfur 80% WG formulations. For residents and bystanders (child and adult), the predicted exposure is also below the background human exposure level.

Considering the representative use of **'Sulphur Dust'** on grapevine (by foliar dusting), the exposure assessment was based on measured exposure for operators, and for workers on a conservative DFR value (0.54 μg/cm^2 of foliage/kg a.s. applied/ha) and DT_{50} (median of 12.6 days) data calculated from field studies. The operator exposure via both dermal and inhalation routes during loading and application of the product is estimated to account for about 15% of the background exposure level, when wearing only standard workwear. Nonetheless, due to the data gap for short term inhalation toxicity study in rodents, the use of respiratory protective equipment (RPE) for operators is recommended. Worker exposure during grape harvesting only relates to the dermal route (EFSA, 2014) and it contributes to just 4.31% of the background exposure level without the use of gloves. Exposure of residents and bystanders is well below the background consumer exposure level (0.6% and 3.4% for adults and children, respectively, without PPE; based on data submitted in a study).

Toxicological studies and information have not been provided for groundwater metabolites, i.e. sulfate. As this is an inorganic compound (not being a heavy metal) it is considered a transformation product of no concern and additional data are not required (European Commission, 2003; see also Evaluation Table Section 2 in EFSA, 2022).

3. Residues

The assessment in the residue section is based on the following guidance documents: OECD, 2009, 2011; European Commission, 2019 and JMPR, 2004, 2007.

Five available publications investigating the fate and metabolism of sulfur (including uptake of sulfate from soil) were already presented and evaluated in the previous renewal assessment (EFSA, 2008b). In one of them the fate of [^{35}S]-labelled micronised sulfur applied to the surface of wheat leaves was studied. Analysis of the surface wash and solvent extract of the leaf material suggested an uptake of around 2% of the applied [^{35}S]-labelled micronised sulfur by treated leaves. In the leaf extracts, 13 radiolabelled compounds were reported and some of them identified as sulfate, cysteine, cystine, methionine, and oxidised and reduced glutathione. The unextractable fraction contained mainly proteins. Another study where only an abstract is available confirmed the finding of limited uptake, this time on oil seed rape leaves. Although not guideline and GLP compliant, the study on wheat can be considered to be valid to elucidate the fate of sulfur when applied to cereals leaves.

These observations were also confirmed by residue field trials with grapes and cereals where the extractable and total sulfur was measured indicting that the major fraction of sulfur remains on the surface. It should be noted that most of the trials were found not valid for various reasons (see reporting table open point 3.2) and that for the representative uses on cereals (both NEU and SEU), grapes (with WG formulations for SEU and NEU) and grapes (with DP formulations for NEU) insufficient numbers of residue trials were presented.

The RMS used the results from the non-valid cereal trials to indicatively complete an animal dietary burden calculation and concluded that the trigger values for all animal species was exceeded mainly due to residues measured in straw.

In the RAR, the RMS estimated consumer exposure of elemental sulfur equivalents from the representative uses in cereals and grapes as well as total sulfur intakes from food using PRIMo 3.1 and from drinking water. It is noted that the exposure from the various authorised sulfur containing food additives such as sulfur dioxide, sulfites and sulfates was not considered in this calculation. Exposure through contribution of food and drinking water seems to be two orders of magnitude higher than exposure from use on cereals and grapes. It is noteworthy that this calculation is only indicative as it is

subject to high uncertainty (e.g. representativeness of food composition database used, use of PRIMo tailored for pesticides and not nutrients, chemical form of sulfur unknown).

Toxicological reference values have not been established (see Section 2 mammalian toxicology) neither have plant and animal residue definitions been derived nor were they considered needed.

Overall, it is concluded that neither additional residue field trials nor animal studies are required, considering that toxicological reference values have not been set.

Following the previous evaluation by EFSA (2008b), sulfur has been included in Annex IV of Commission Regulation (EU) No 459/2010[5] of 27 May 2010 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products.

With regard to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for inclusion in Annex IV of Regulation (EC) No 396/2005, i.e.: approval as basic substance (criterion I), listed in Annex I of Regulation (EC) No 396/2005 (criterion II), having no identified hazardous properties (criterion III), natural exposure is higher than the one linked to the use as plant protection product (criterion IV) and consumer exposure is not expected considering the representative uses (criterion V); two criteria were considered to remain met for sulfur for the following reasons:

Toxicological reference values are not required for sulfur (criterion III) (see Section 2). The natural exposure from natural sulfur compound sources present in food (e.g. as amino acids, proteins, etc.) is higher than the one linked to the uses assessed in this conclusion as plant protection products (criterion IV). The other three criteria (criteria I, II and V) are not fulfilled.

4. Environmental fate and behaviour

Sulfur was discussed at the Pesticides Peer Review Experts' Teleconference 86 in July 2022.

Elemental sulfur, as well as many of its inorganic and organic compounds, are considered ubiquitous in nature and are commonly found in the three environmental compartments (soil, water and air). The sulfur cycle is well known and the processes that govern the behaviour of naturally occurring sulfur in the environment also govern the fate of sulfur added as an application as a fungicide or acaricide.

Sulfur, as an element, cannot degrade or break down. However, it does undergo oxidation to sulfate or reduction to sulfide by certain microorganisms and microorganism communities. Soluble compounds of sulfur are made available for uptake by plants and animals contributing to the natural functions of sulfur as an essential element needed for the life of organisms. Under agriculture conditions oxidation is the most dominant process in the top soil and sulfate is by far the most common form of inorganic sulfur in nature.

Reliable total sulfur concentration data on background levels in agriculture soils were provided by the applicant. Experts proposed to not add these to the PEC_{soil} calculations. However, agriculture background concentration of sulfate in soil is difficult to establish as the level of sulfate in soils can be present at a wide range of concentrations that can vary spatially and temporally. Moreover, it has to be noted that elemental sulfur is applied to soil as an amendment treatment or as a fertiliser.

The rate of oxidation of elemental sulfur is the process that determines the rate at which sulfate is available to plants and other organisms. The statement from the previous evaluation for renewal of the active substance (EFSA, 2008b) that available information only enables a qualitative assessment on the oxidation rates of elemental sulfur to sulfate remains valid. The complexity of the process governing the oxidation rates and the lack of information on any method for the calculation of oxidation rates prevented a quantitative determination of DT_{50} for aerobic and anaerobic soil transformations.

Sulfur is not expected to be persistent in its elemental form, and therefore accumulation of elemental sulfur in soil is not expected. However, sulfate ion levels are highly variable, prone to fast dissipation and can be present as a result of different natural and anthropogenic sources other than the use of elemental sulfur as a pesticide active substance.

Sulfur is not adsorbed to soil particle surfaces. Adsorption of sulfur was estimated from the water solubility (16 μg/L) as essentially resulting in immobility in soil. Inorganic sulfur compounds are more mobile, especially sulfate. Further studies on sulfate's adsorption were considered unnecessary because

[5] Commission Regulation (EU) No 459/2010 of 27 May 2010 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 129, 28.5.2010, pp. 3–49.

sulfate ions predominate in natural soils and are incorporated in natural sulfate ion concentrations. A pH-dependency of soil sorption cannot be excluded for sulfate, with it exhibiting a general tendency for soil sorption to decrease with increasing soil pH.

In a lysimeter study of 3 years duration receiving elemental sulfur or sulfate fertilisers, results indicated very limited leaching of sulfur, while sulfate was highly mobile and prone to leaching under the experimental conditions.

Sulfur itself is practically insoluble in water. Thus, when sulfur enters an aquatic system, it is expected to precipitate and preferentially adsorb to sediment and then be oxidised. Sulfur, being an element, is considered not readily biodegradable, due to its low solubility in water and for the fact that by definition it cannot be mineralised (it already being a mineral). Hydrolysis and aerobic mineralisation in surface water were not investigated for the same reasons. It was accepted that studies investigating these processes were not required. Since the cycle of sulfur in the environment is well understood, the literature provided was considered sufficient to address the route and rate of degradation of sulfur in natural aquatic systems. Sulfur is not expected to be persistent in its elemental form in both surface water and sediment compartments, therefore accumulation of elemental sulfur in sediment is not expected.

The necessary surface water and sediment exposure assessments (predicted environmental concentration (PEC) calculations) were carried out for sulfur and sulfate using the FOCUS step 1 and step 2 (version 3.2 of the Steps 1–2 in FOCUS calculator). PEC_{sw} for sulfur considering the spray drift deposition rates for a single application, as agreed by experts during the Teleconference 86 meeting, as well as with the approach proposed in the previous evaluation (EFSA, 2008b) of setting the PEC_{sw} to the maximum water solubility, are available. The two approaches reflect both the total (dissolved + non-dissolved) and dissolved sulfur concentrations in water, respectively.

For the PEC_{sed} calculations (calculated according to the risk envelope approach), the experts agreed to not add the background levels as the sulfur present, and consequently sulfate produced, will flow through the water body systems. However, the calculated PEC_{sed} values for sulfur were in the range of the background concentrations of total sulfur that are available for stream and floodplain sediments. Considering that a pH-dependency of soil sorption cannot be excluded for sulfate (i.e. soil sorption decreases with increasing pH value), a similar behaviour is expected also for sediment and therefore a maximum default value for the soil adsorption coefficient of sulfate was used to cover all situations in Europe, in the absence of more reliable values.

Sulfur arriving in topsoil from the intended uses is not of concern for the contamination of groundwater due to its immobility. PEC_{gw} were estimated for sulfate, it being the oxidation product, which is soluble in water and highly mobile in soil. As agreed by experts at the Teleconference 86 meeting, PEC_{gw} were estimated for sulfate considering only the newly added sulfur in soil following the application of the formulated products and without taking into account other possible anthropogenic sources or the background level of total sulfur in soil. The calculations provided according to the risk envelope approach were based on the conservative assumption that 100% of the applied sulfur will leach to groundwater and is completely oxidised to sulfate (1 S_8 to produce 8 SO_4^{2-}).

The applicability of using the FOCUS modelling for inorganic compounds was discussed by experts and it was concluded that in this case, considering the fast oxidation rates, the FOCUS modelling can be accepted. The potential for groundwater exposure from the representative uses by elemental sulfur was confirmed as unnecessary. The necessary groundwater exposure assessments for sulfate were appropriately carried out using FOCUS (European Commission, 2014b) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4.[6] For sulfate, the estimated 80th percentile annual average recharge concentrations moving below 1 m were:

- < 250 mg/L in all nine scenarios and six scenarios, for the representative use in winter and spring cereals, respectively (for sulfur 80% WG products);
- < 250 mg/L in all seven scenarios for the representative use in vines (for sulfur 80% WG products);
- > 250 mg/L at three out of seven scenarios for the representative use in vines (for Sulphur Dust).

[6] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008a) and Walker equation coefficient of 0.7.

It should be noted that PEC_{gw} have been compared with the value of 250 mg/L, set as an indicative parameter for sulfate in both the applicable Drinking Water Directives.[7,8]

The applicant provided appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water. The conclusion of this consideration was that no supplemental residues from oxidation/reduction of sulfur or sulfate deriving from application of the PPPs are expected to be formed in relevant concentrations during water treatment processes. Moreover, sulfate is already present as dissolved ions in ground- and surface water originating from several different sources.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix B of this conclusion. A key to the wording used to describe the mobility of the compounds assessed can be found in Appendix C of this conclusion.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b), SETAC (2001), EFSA (2009, 2013) and EFSA PPR Panel (2013).

Sulfur was discussed at the Pesticide Peer Review Experts' Teleconference 87 which took place in July 2022.

The information to support the compliance of the batches used in the ecotoxicological studies with the technical specification (both the proposed updated reference specification and the current reference specification) was considered sufficient.

In the available acute toxicity studies for **birds** and **mammals**, signs of toxicity were not observed, and the endpoints were derived as greater than values. Long-term toxicity studies for birds and mammals were not available. For mammals, low acute risk was concluded for all representative uses. At tier-1 risk assessment, high acute risk to birds was indicated for several combination of uses/ indicator species. By using an extrapolated LD_{50} value, a low risk could be concluded except for insectivorous, granivorous and omnivorous birds at BBCH $\geq$ 10 and frugivorous birds at ripening for the uses with Sulphur Dust on grapevine, and for frugivorous birds at ripening for the uses with Sulfur 80% WG products on grapevine. To address the remaining risks for birds, several refinements were discussed at the experts' meeting (e.g. use of an updated deposition factor, refinement of residue unit dose values).[9] A low risk to insectivorous birds at BBCH 10–19 for the uses of Sulphur Dust on grapevine could be concluded when considering the updated deposition factor. At the expert meeting, the following lines of evidence were considered: (i) the specific exposure condition of sulfur; (ii) that sulfur is an essential element needed at high intake levels; (ii) the long history of uses (including pharmaceutical and as a fertiliser) without adverse outcomes having been reported; (iii) background exposure to sulfur is high as it is ubiquitous in nature and commonly found in soil and water (see Section 4); (iv) the additional sulfur being added to the environment from representative uses assessed is limited compared to other natural and anthropogenic sources; (v) that the acute studies showed no toxicity. Therefore, it was agreed that long term studies with birds and mammals can be waived. Overall, based on a weight of evidence approach considering the above lines of evidence, the experts at the meeting agreed to conclude a low acute and reproductive risk to birds and mammals for all representative uses (see Sections 2 and 4). The same conclusion applied to plant metabolites. A low risk was also concluded for secondary poisoning and from consumption of contaminated water for all representative uses.

Toxicity studies were available with both the representative formulation types (WG and dust) to address the risk to **aquatic organisms**. The risk assessment approach was discussed at the experts' meeting.[10] Overall, it was noted that since the concentrations used in the tests were much higher than the limit of solubility of sulfur, the organisms were exposed to both soluble and insoluble sulfur. No adverse effects were observed in the available studies for fish and aquatic invertebrates. The effect on growth observed in the algal study was attributed to the light inhibition from suspended particles during the test and it was considered unlikely to occur following the representative uses in the

[7] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1988, pp. 32–54.
[8] Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption. OJ L 435, 23.12.2020, pp. 1–62.
[9] Refer to experts' consultation 5.1 in the Report of Pesticides Peer Review Experts' Teleconference 87 (EFSA, 2022).
[10] Refer to experts' consultation 5.2 in the Report of Pesticides Peer Review Experts' Teleconference 87 (EFSA, 2022).

environment. The water solubility limit was proposed as an endpoint for all studies with aquatic organisms. Considering the above, low acute and chronic risk for all aquatic organisms in the water column was concluded for all representative uses.[10] At the expert meeting, it was concluded based on the available information the risk could not be refined for sediment-dwelling organisms for intended uses for sulfur. However, after the meeting the environmental fate assessment concluded that accumulation of elemental sulfur in sediment is not expected to occur (see Section 4), therefore EFSA concluded a risk assessment was not considered necessary, and a low risk could be concluded for sediment-dwelling organisms for all representative uses.[11] Considering sulfate as a pertinent metabolite that accumulates in sediment (see Section 4), a risk assessment for sediment-dwelling organisms was required. A spiked-water toxicity study for *Chironomus riparius* with sulfate and a spiked-sediment toxicity study conducted with Sulfur 80% WG were available. Using the lowest NOEC from the available dataset, a high risk to sediment dwellers was identified following FOCUS Step 2 PEC_{sw} for all uses. Nevertheless, a low risk could be concluded for sediment-dwelling organisms for the uses of Sulfur 80% WG based on the following: (i) the PEC/RAC-ratios are close to the trigger in the case of cereals and grapevine, (ii) further refinements based on exposure estimates at FOCUS Step 3 could not be conducted because PECs at FOCUS Step 3 could not be estimated due to the limitations of the current existing model,[12] and (iii) in both toxicity studies with chironomids species exposure to sulfate was assumed to occur and no effects were observed (i.e. endpoints were set as greater than values) . Based on the above-mentioned arguments a low risk could not be concluded for sediment-dwellers when Sulphur Dust is used. Thus, a high risk remains unresolved. (data gap; see Section 10).

Acute oral and contact toxicity studies on honey **bees** were carried out with the representative formulations. Toxicity data with the a.s. were not available. Nevertheless, studies performed with Sulphur Dust were considered as surrogate given the nature of sulfur and the composition of the formulation (i.e. specified as 985 g/kg (98.5% a.s.) with an inert carrier as only co-formulant). Low acute (oral and contact) risk was identified for all representative uses on cereals and grapevine based on the SANCO guidance on terrestrial ecotoxicology (European Commission, 2002a). Following the EFSA (2013) risk assessment scheme, the same conclusion was reached for the uses with different sulfur 80% WG products but a high acute oral risk for the use of Sulphur Dust was identified. Based on EFSA (2013), a high chronic risk to adults and larvae was indicated for all the uses with all the representative formulations at the screening step. At tier 1, high chronic risk was identified for adults ('treated crop', 'flowering weeds' and 'succeeding crop' scenarios), and for larvae (all relevant scenarios) for the use of Sulphur Dust on grapevine. In the case of sulfur 80% WG products, high chronic risk was identified for adults ('treated crop' and 'flowering weeds' scenarios) and larvae ('treated crop', 'flowering weeds' and 'succeeding crop' scenarios) for the uses on cereals and grapevine.[13] To refine the risk, two semi-field (tunnel) studies were available with both formulation types and discussed at the experts' meeting.[12] The majority of the experts agreed that the higher tier studies could not be used to refine all the scenarios where high risk had been identified. The study design of both tunnel studies did not mimic the maximum seasonal use pattern as reported in the GAPs where multiple applications are intended; therefore, the studies were considered unsuitable for refining the risk. Therefore, high chronic risk remained indicated for honey bee larvae and adults for all representative uses (data gap, see Section 10). The risk from exposure to contaminated water was not assessed (data gap, see Section 10). A suitable assessment for accumulative and sublethal effects (e.g. hypopharyngeal glands) was not available (data gap for sub-lethal effects, see Section 10). A risk assessment for metabolites was not available; however, based on the assessment of the nature of plant residues (see Section 3) it is expected that dietary exposure to bees would be low, thus, a low risk could be concluded for non-elemental sulfur plant residues for all representative uses.

For **non-target arthropods** other than bees, tier 1 (glass plate) and extended laboratory studies with the standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* and the additional species *Trichogramma cacoeciae*, *Poecilus cupreus* and *Chrysoperla carnea* were available with both representative formulation types. By using the available data and risk assessment, high in-field risk was indicated for all uses and for all tested species, except for *C. carnea*, for which a low risk could be concluded for the uses with the Sulfur 80% WG products, and for *P. cupreus* for the uses with Sulphur Dust. Several refinement options were discussed at the experts' meeting.[14] Although certain

[11] Please note that the RMS expressed disagreement with this conclusion following a written procedure.
[12] Refer to experts' consultation 4.3 in the Report of Pesticides Peer Review Experts' Teleconference 86 (EFSA, 2022).
[13] Refer to experts' consultation 5.3 in the Report of Pesticides Peer Review Experts' Teleconference 87 (EFSA, 2022).
[14] Refer to experts' consultation 5.4 in the Report of Pesticides Peer Review Experts' Teleconference 87 (EFSA, 2022).

deficiencies were identified in the aged-residue study with the most sensitive species (*T. cacoeciae*) with Sulfur 80% WG products (e.g. influencing/confounding effects, wash-off of sulfur due to precipitation), it was noted that recovery and recolonisation of the organisms appeared to be hampered. All available aged-residue studies with Sulphur Dust were considered not reliable by the experts. Therefore, low in-field risk could not be concluded for any of the representative uses. A low off-field risk could be concluded for the uses on cereals with Sulfur 80% WG products with the implementation of a 5-m buffer zone. For the uses on grapevine with Sulfur 80% WG products, a low off-field risk could be concluded with the implementation of buffer zones (10 m for early applications and 20 m for late applications). The off-field risk for use of Sulphur Dust on grapevine could not be finalised as suitable drift values were not available to derive reliable environmental concentration predictions.[15] Based on the outcome of the risk assessment for non-target arthropods other than bees, a critical area of concern was identified (see Section 9). Based on the information in the available study, it should be noted that the latest (autumn) and earliest (spring) applications could not ensure the recovery the recovery of sensitive NTA population.

Chronic toxicity studies were available with **earthworms** and **other soil macroorganisms** with Sulphur Dust.[15] Low chronic risk could be concluded for *E. fetida* and *H. aculeifer* while high risk was concluded for *F. candida* for the uses with Sulfur 80% WG products. For the use of Sulphur Dust, a high risk was concluded for all soil macroorganisms. To refine the risk, three field studies with soil macroorganisms were notified as having been initiated (one earthworm study with Sulphur Dust and a collembolan study with the each of the representative formulation types); however, as only interim reports were available the experts at the meeting considered that the information provided did not allow to draw a firm conclusion.[16] Therefore, high risk remained for all representative uses (critical area of concern; see Section 9).

Based on the available data, a low risk can be concluded for all representative uses for **soil micro-organisms**, **non-target terrestrial plants** and **organisms involved in biological methods for sewage treatment**.

6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption potential of sulfur for humans and non-target organisms according to the ECHA/EFSA ED guidance (ECHA/EFSA, 2018), although no (eco) toxicological data are available to assess the endocrine-disrupting properties, this does not appear scientifically necessary for the following reasons:

- Sulfur is an ubiquitous element with a wide range of background exposures and humans and non-target organisms are consistently exposed to sulfur and its oxidised forms that originate from a wide range of sources and in a variety of ways[17];
- The use of sulfur as a plant protection product is considered to lead to an inconsequential contribution to the overall exposure in comparison to the exposure under natural conditions (see Section 3);
- Sulfur is an essential nutrient for animal and plant functions (e.g. constituent of amino acids) and the minimum daily intake is pretty high[18];
- In addition, sulfur itself is practically insoluble in water (see Section 4) and therefore, poorly bioavailable for aquatic organisms in natural conditions;
- Sulfur is characterised by low acute and short-term toxicity toward vertebrates in the available toxicity studies and it does not have genotoxic potential. Moreover, toxicological reference values were not derived for the substance (see Section 2).

Based on the available information, it can be concluded that it is unlikely that sulfur meets the criteria for endocrine disruption 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.

[15] The endpoints derived from the studies with Sulfur Dust were used for the risk assessment for the representative uses with Sulfur 80% WG.
[16] Refer to experts' consultation 5.5 in the Report of Pesticides Peer Review Experts' Teleconference 87 (EFSA, 2022).
[17] Added to foods as preservative agents and for other purposes. Sulfites are added to foods due to their properties as bleaching agents, antimicrobials, oxygen scavengers, reducing agents, and enzyme inhibitors. Further, sulfites act as preservatives in pharmaceutical and cosmetic products (Garcia-Fuentes et al., 2015; Halla et al., 2018).
[18] The minimum WHO recommendation of daily intake of sulfur amino acids is 15 mg/kg bw (FAO, 2007).

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)	Ecotoxicology
Sulfur	High risk for soil organisms[(a)]

(a): High risk for earthworms for the uses with Sulphur Dust on grapevine and high risk for Collembola for all representative uses.

Table 2: Groundwater

Compound (name and/or code)[(a)]	> 0.1 µg/L at 1 m depth for the representative uses[(b),(c)] Step 2	Biological (pesticidal) activity/ relevance Step 3a	Hazard identified Steps 3b and 3c	Consumer risk assessment triggered Steps 4 and 5	Human health relevance
sulfur[(c)]	Not relevant	Yes	Not triggered	–	Not triggered
sulfate[(c)] (oxidation product of sulfur)	**Yes** Vines (29.55 kg/ha dustable powder) 3/7 FOCUS scenarios (255.10–459.63 mg/L) **No** For representative uses in vines (10 kg/ha water dispersible granular), winter and spring cereals	–	Not applicable. A drinking water directive value indicator parameter is set.	No	No

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003) important note, not applicable for inorganic compounds where degradation products are considered of 'no concern'.
(b): FOCUS scenarios or relevant lysimeter. Ranges indicated for FOCUS scenarios include the result from the model giving the highest concentration at each scenario, as needed to comply with European Commission (2014b) guidance.
(c): Sulfur is an inorganic element and sulfate is an inorganic compound. The parametric drinking water limit of 0.1 µg/L for pesticides and their relevant metabolites as defined by the drinking water directive 98/83/EEC[7] is not applicable. However, the drinking water directive 98/83/EEC sets a value of **250 mg/L as an indicator parameter for sulfate**.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Sulfur	Low risk for all aquatic organisms
sulfate (oxidation product of sulfur)	High risk for sediment-dwelling organisms for Sulphur Dust representative use

Table 4: Air

Compound (name and/or code)	Toxicology
sulfur (particulate S)	> 5.43 mg/L air 4 h (nose only)

8. Particular conditions proposed to be taken into account by risk managers

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms

for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level (Table 5).

Table 5: Risk mitigation measures proposed for the representative uses assessed

Representative use	sulfur WG - Grapevine	sulfur WG		Sulphur Dust Grapevine
		Winter Cereal	Spring Cereal	
	foliar spray	foliar spray	foliar spray	foliar dust
Operator risk				Use of RPE is recommended
Bystander/resident exposure	Buffer strip 2–3 m	Buffer strip 2–3 m	Buffer strip 2–3 m	Buffer strip ≤ 5 m
Off-field risk to non-target arthropods other than bees	RMM equivalent to a 10-m (for early application) and a 20-m buffer zone (for late application).	RMM equivalent to a 5-m buffer zone	RMM equivalent to a 5-m buffer zone	

9. Concerns and related data gaps

9.1. 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 one or more of 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[19] 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.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

- Assessments not finalised were not identified.

9.2. 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.

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.

[19] 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, pp. 127–175.

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.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

1) High in-field risk to non-target arthropods other than bees for all representative uses (see Section 5).
2) High risk to soil macroorganisms for all representative use (see Section 5).

9.3. Overview of the concerns identified for each representative use considered (Table 6)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 6).

In addition to the issues indicated in Table 6 below, the technical material specification proposed was not comparable to the material used in the testing that was used to derive the toxicological reference values.

Table 6: Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios

Representative use		Winter Cereals	Spring Cereals	Vines	Vines
		foliar spray	foliar spray	foliar spray	foliar dust
Operator risk	Risk identified				
	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	X[1,2 (b)]	X[1,2 (b)]	X[1,2 (b)]	X[1,2 (b)]
	Assessment not finalised				
Risk to aquatic organisms	Risk identified				X[(c)]
	Assessment not finalised				
Groundwater exposure to active substance	Legal parametric value breached				
	Assessment not finalised				
Groundwater exposure to metabolites	Parametric indicator value breached				3/7 FOCUS scenarios
	Parametric value of 10 µg/L[(a)] breached				
	Assessment not finalised				

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 4 and 7 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.
(b): High chronic risk to honeybee larvae and adults for all representative uses were identified based on EFSA (2013).
(c): High risk for sediment-dwelling organisms for sulfate relevant for Sulphur Dust representative use.

10. List of other outstanding issues

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections:

- The test material used in toxicity studies cannot be concluded as fully representative of the proposed reference specification for the active substance and associated impurities (see Sections 1 and 2).
- Sulfur was not phototoxic in the OECD 3 T3 NRU-PT test. However, the OECD 3 T3 NRU-PT might not allow concluding properly on the phototoxicity potential of sulfur since it is an UVB absorber and the 3 T3 NRU-PT test might not be an appropriate test for UVB absorbers. It is noted however that phototoxicity testing applying the new version of the OECD TG 432 (June, 2019) would allow for proper assessment of UVB absorbers; amiodarone, an UVB absorber could be used as positive control (relevant for all representative uses evaluated; see Section 2).
- The repeated dose toxicity by inhalation of sulfur should be addressed (relevant for the representative use of Sulphur Dust; see Section 2).
- *In vitro* human dermal absorption study with sulfur 80% WG once the default dermal absorption value of 10% should not apply (relevant for the sulfur 80% WG; study ongoing, see list of endpoints section human health).
- A data gap was identified for Zolfital to provide data on the manufacturing of the technical active substance (see confidential evaluation table for Zolfital) (see Section 1).
- A data gap was identified for STF to provide validated analytical methods with adequate LOQs for the determination of the relevant impurity mercury, arsenic, chromium and cadmium in the formulation 'Sulphur Dust' (see Section 1).
- A data gap was identified for SWG to provide validated analytical methods with adequate LOQs for the determination of the relevant impurities mercury, arsenic and cadmium in the formulations 'KUMULUS WG' (BASF), 'Thiovit Jet' (Syngenta), 'Netzschwefel Stulln' (Agrostulln) and 'Microthiol Special Disperss' (UPL) (see Section 1).
- Valid FOCUS Step 2 approach PEC calculations for sulfate with drift of sulfur mitigated to further address the risk for sediment-dwelling organisms (relevant for all representative uses; see Sections 4 and 5).
- Further data are needed to address the risk to sediment-dwelling organisms for the use on grapevine with Sulphur Dust (see Section 5).
- Further data were not available to address the risk to honeybees from sublethal effects (e.g. effects on hypopharyngeal glands) and the risk from exposure to contaminated water (relevant for all representative uses, see Section 5).
- Further data to address the high chronic risk for adults and larvae honey bees (see Section 5).

References

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Abbreviations

a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
ADME	absorption, distribution, metabolism and excretion
AFEPASA	Azufrera y Fertilizantes Pallarés, S.A.
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
DAR	draft assessment report
DP	dustable powder
DT_{50}	period required for 50% dissipation (define method of estimation)
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 spectrometry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LOQ	limit of quantification
MRL	maximum residue level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PPE	personal protective equipment
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
STF	Sulphur Task Force

SWG	Sulfur Working Group
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Consideration of cut-off criteria for sulfur according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[(a)]
CMR	Carcinogenicity (C)	Sulfur is not considered to be mutagenic, carcinogenic or toxic for reproduction according to points 3.6.2, 3.6.3 and 3.6.4 of Annex II of Regulation(EC) 1107/2009.
	Mutagenicity (M)	
	Toxic for Reproduction (R)	
Endocrine-disrupting properties		Sulfur is not considered to meet the criteria for endocrine disruption for human health and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
POP	**Persistence**	Sulfur is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	Sulfur is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	
	Toxicity	
vPvB	**Persistence**	Sulfur is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	

(a): Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

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

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2023.7805

Appendix C – Wording EFSA used in Section 4 of this conclusion, in relation to K_{oc} 'classes' exhibited by each compound assessed

Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
very high mobility	0 to 50
high mobility	51 to 150
medium mobility	151 to 500
low mobility	501 to 2,000
slight mobility	2,001 to 5,000
immobile	> 5,000

Based on McCall et al. (1980).