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CONCLUSION ON PESTICIDE PEER REVIEW

Peer review of the pesticide risk assessment of the active substance sulfur[1]

Question No EFSA-Q-2008-393

Issued on 19 December 2008

SUMMARY

Sulfur is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[2], as amended by Regulation (EC) No 1095/2007[3]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

France being the designated rapporteur Member State submitted the DAR on sulfur in accordance with the provisions of Article 21(1) of the Regulation (EC) No 2229/2004, which was received by the EFSA on 18 October 2007. The peer review was initiated on 18 February 2008 by dispatching the DAR for consultation of the Member States and the notifiers Sulfur Task Force and Sulfur Working Group. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by the EFSA to identify the remaining issues. The identified issues as well as further information made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in October 2008.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in December 2008 leading to the conclusions as laid down in this report.

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[1] For citation purposes: Conclusion on pesticide peer review regarding the risk assessment of the active substance sulfur. *EFSA Scientific Report* (2008) 221, 1-70

[2] OJ No L 379, 24.12.2004, p.13

[3] OJ L 246, 21.9.2007, p. 19

This conclusion was reached on the basis of the evaluation of the representative uses as a fungicide on cereals and grapes. Sulfur is also known to have acaricidal properties. Full details of the GAP can be found in the endpoints.

The representative formulated products for the evaluation were ‘Thiovit Jet 80 WG’, ‘Microthiol Disperss’, ‘Kumulus WG’, ‘Netzschwefel Stulln’ and ‘Sulphur 80 WG’ water dispersible granule formulations (WG) and ‘Sulphur Dust’ a dustable powder formulation (DP).

Monitoring methods are not required; see sections 3, 4 and 5.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection products are possible. Some physical and chemical properties are missing, and some of the sources need 5-batch data.

Sulfur is generally regarded as safe for human exposure given the wide range of background exposure, since it is naturally present and abundant in food, where it can be found in the form of sulfate, free amino acids, proteins and vitamins, and it is an essential element needed at a high dose level. Toxicological studies showed that sulfur has a low acute oral, dermal and inhalation toxicity. It is a skin irritant but not an eye irritant, nor a skin sensitizer. The following classification was proposed: **Xi, R38 “Irritating to the skin”**. Sulfur has also a low short-term oral toxicity, since the NOAEL in a 28-day and 90-day rat study was the highest dose level tested (1000 mg/kg bw/day). The weight of evidence indicates that sulfur is not a genotoxic agent. Thus, since sulfur is an essential element, and considering its wide range of background exposure, its low acute and short-term toxicity and its lack of genotoxic potential, long-term toxicity, carcinogenicity- and reproductive toxicity studies were not performed, neither they were required. Likewise, it was agreed not to propose an ADI, AOEL and ARfD. Operator, bystander and worker exposure to sulfur 80% WG products was considered negligible compared to the wide range of background level.

Residues do not need to be considered as the mammalian toxicology assessment has concluded that sulfur is of low toxicity, and it is not necessary to set an ADI or ARfD. Therefore, a consumer risk assessment is neither possible nor necessary.

Sulfur degradation in soil is governed by oxidation. The available data on the rate of oxidation of sulfur in soil were considered valid by the peer review only from a qualitative point of view. It has been shown that the oxidation rate of sulfur increases with the particle size of the elemental sulfur used, and with temperature. Sulfur exhibits low mobility in soil. A conservative estimation of the Koc value for sulfur was derived from the water solubility value. Results from the available lysimeter study indicated that sulfates (the main oxidation product of sulfur in soil) were highly mobile and prone to leaching under the experimental conditions, whereas the slow release characteristics of elemental sulfur led to smaller leaching losses. An evaluation based on the worst case in terms of sulfur application rate on grapes (30 kg S/ha, 5 times a year, 85 % crop interception), assuming that 100 % of sulfur applied to soil is oxidised to sulfates and 100 % of sulfates will leach to groundwater, showed that there was no unacceptable (< 250 mg/L) contamination of groundwater expected from sulfates.

Sulfur is slightly soluble in water. Specific data on behaviour of sulfur in natural aerobic water/sediment systems is not available. However, the peer review considered the available information sufficient to complete an aquatic exposure assessment at EU level for the applied for intended uses. No PECsw values were calculated, as the risk assessment to aquatic organisms was performed taking into account an absence of effects to organisms at the highest water solubility limit of sulfur. New calculations for PECsed were provided by the rapporteur Member State after the PRAPeR meeting; however, as the new calculations were based on inappropriate input parameters, the EFSA identified a data gap to address the exposure assessment for the sediment compartment.

The acute and short-term risk to insectivorous birds was low for the representative use in cereals and vineyards at application rates of 2 x 4.8 kg a.s./ha and 8 x 2.56 kg a.s./ha, respectively. The risk to herbivorous birds needs further refinement for the uses in cereals (early application). The risk to insectivorous birds needs to be refined further for the uses in cereals at an application rate of 2 x 6.4 kg a.s./ha, and for the uses in vineyards at application rates of 8, 19.7 and 29.5 kg a.s./ha. The risk to mammals was assessed as low for the uses in cereals and the use in vineyards at an application rate of 8 x 2.56 kg a.s./ha. Further refinement of the risk assessment is needed for application rates in vineyards of 8 x 8, 5 x 19.7 and 5 x 29.5 kg a.s./ha. Some uncertainty remains with regard to the long-term risk to birds and mammals. The experts considered it necessary to address this uncertainty with further and more detailed information/data.

The risk to aquatic organisms in the water column was considered in general as low, because the solubility of sulfur in water is very low and no effects were observed at concentrations, which exceeded the water solubility by several orders of magnitude. Uncertainty remains with regard to the risk to sediment-dwelling organisms, and a study with *Chironomus riparius* was considered necessary.

The hazard quotient (HQ) values for bees indicated a low risk to bees for the uses in cereals and in vineyards at an application rate of 2.56 kg a.s./ha. The HQ values exceeded the Annex VI trigger of 50 for all other uses in vineyards. The experts considered the risk to bees likely to be low, because no mortality of bees was observed at the highest tested doses. It was suggested in the meeting that the uncertainty with regard to the risk to bees from application rates of 8, 19.7 and 29.5 kg a.s./ha in vineyards should be addressed further at Member State level, considering also risk mitigation measures.

The risk to sensitive non-target arthropods (parasitoids) was not demonstrated to be low in the available risk assessment. Further higher tier testing, e.g. field studies or aged residues tests, are required to provide evidence that recolonisation of the in-field area by sensitive hymenoptera is possible within 1 year.

No studies were submitted with activated sewage sludge. It was considered that sulfur would not reach sewage treatment plants in significant amounts, and therefore no studies were considered necessary.

The risk to earthworms, other soil non-target macro-organisms, soil non-target micro-organisms, non-target terrestrial plants was assessed as low.

Key words: sulfur, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

Commission Regulation (EC) No 2229/2004 laying down the detailed rules for the implementation of the fourth stage of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 1112/2002, as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Sulfur is one of the 295 substances of the fourth stage, covered by the amended Regulation (EC) No 2229/2004 designating France as rapporteur Member State.

In accordance with the provisions of Article 21(1) of the Regulation (EC) No 2229/2004, France submitted the report of its initial evaluation of the dossier on sulfur, hereafter referred to as the draft assessment report, received by the EFSA on 18 October 2008. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 24(2) of the Regulation (EC) 1095/2007 on 18 February 2008 to the Member States and to the main applicants Sulfur Task Force and Sulfur Working Group, as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, the EFSA identified and agreed on lacking information to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in expert meetings in October 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in December 2008 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR).

In accordance with Article 24c(1) of the amended Regulation (EC) No 2229/2004, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant endpoints for the active substance as well as the formulation is provided in appendix A.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State’s draft assessment report:

- the comments received,
- the resulting reporting table (revision 1-1, 9 June 2008),

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation,
- the evaluation table (revision 2-1, 19 December 2008).

Given the importance of the draft assessment report including its addendum (compiled version of December 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Sulfur has no ISO common name.

Sulfur is a non-specific thiol reactant, inhibiting respiration. It is a non-systemic, protective fungicide with contact and vapour action.

The evaluated representative uses are as a fungicide on cereals and grapes. Full details of the GAP can be found in the list of endpoints. Sulfur is also known to have acaricidal properties.

The representative formulated products for the evaluation were 'Thiovit Jet 80 WG', 'Microthiol Disperss', 'Kumulus WG', 'Netzschwefel Stulln' and 'Sulphur 80 WG' water dispersible granule formulations (WG) and 'Sulphur Dust' a dustable powder formulation (DP).

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of sulfur as manufactured should not be less than 990 g/kg. At the moment no FAO specification exists for technical sulfur. It should be noted that 5-batch data remain a data gap for all members of the Sulfur Working Group, except CITIS. Starting materials (including catalysts) and methods of manufacture for the Sulfur Working Group and the Sulfur Task Force are also identified as data gaps. For the Sulfur Task Force for the mined sulfur sources Quimetal and Zaklady the 5-batch data were rejected, because there was no arsenic analysis.

According to the equivalence assessment, the supported sources, namely CITIS, Cepsa, Petrogal, Repsolypf, Solfotecnica, Sulphur Mills, Zolfital and Zolfindustria are equivalent. All have a minimum purity of 990 g/kg with no significant or relevant impurities.

The content of sulfur in the representative formulation is 80 % w/w for the WG formulations and 98.5 % for the dustable powder.

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 sulfur or the respective formulations.

The main data regarding the identity of sulfur and its physical and chemical properties are given in appendix A.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also, adequate analytical methods are available for the determination of sulfur in the technical material and in the representative formulations, as well as for the determination of the respective impurities in the technical material.

Therefore, enough data are available to ensure that quality control measurements of the plant protection products are possible. Nevertheless, it should be noted that there are data gaps for some of the individual formulations (refer to chapter 'List of studies to be generated, still ongoing or available but not peer reviewed'). It was also discovered when writing the conclusion that a data gap for the formulation 'Netzschwefel Stulln' was missed, namely attrition resistance.

Monitoring methods are not required; see sections 3, 4 and 5. A method for body fluids and tissues is also not required as sulfur is neither toxic nor highly toxic.

2. Mammalian toxicology

Sulfur mammalian toxicology was discussed at the PRAPeR 59 meeting of experts in October 2008.

Sulfur is an essential element and it is needed at high dose levels. It is generally regarded as safe for human exposure given the wide range of background exposure, since it is naturally present and abundant in food, where it can be found in the form of sulfate, free amino acids, proteins and vitamins.

The 80% WG products (‘Thiovit Jet 80 WG’, ‘Microthiol Disperss’, ‘Kumulus WG’, ‘Netzschwefel Stulln’ and ‘Sulphur 80 WG’) were considered to be similar, therefore, dermal absorption values and exposure assessment of the 80 % WG formulations were assessed together, combining all available data.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

No studies on absorption, distribution, metabolism and excretion of sulfur in animals were submitted. Nevertheless, published human studies showed that it is well absorbed at low dose levels. Sulfur is uniformly distributed. It has no potential for accumulation. Sulfur is an essential element and the homeostasis is maintained. Sulfur is extensively metabolised to sulfates and sulfites.

2.2. Acute toxicity

Sulfur has a low acute toxicity to rats after oral, dermal and inhalative administration (oral LD_{50} > 2000 mg/kg bw, dermal LD_{50} > 2000 mg/kg bw, LC_{50} > 5.43 mg/L air over 4 hours). It is a skin irritant but not an eye irritant, nor a skin sensitizer in the guinea pig maximization test. The following classification was proposed: **Xi, “irritant”,** and risk phrase **R38 “Irritating to the skin”**.

2.3. Short-term toxicity

The short-term effects of sulfur were studied in rats. Sulfur has also a low short-term oral toxicity, since the NOAEL in a 28-day and 90-day study was the highest dose level tested (1000 mg/kg bw/day). The relevant dermal NOAEL was 400 mg/kg bw/day based only on local reversible dermal hyperkeratosis at 1000 mg/kg bw/day.

2.4. Genotoxicity

Three genotoxicity studies were performed with sulfur including *in vitro* gene mutation assay in bacteria, and *in vitro* and *in vivo* clastogenicity studies. Negative results were found in all studies. Thus, the weight of evidence indicates that sulfur is not a genotoxic agent.

2.5. Long-term toxicity

No long-term toxicity and carcinogenicity studies were performed, as sulfur is generally regarded as safe for human exposure given the wide range of background exposure, its low acute and short-term toxicity and its non-genotoxic potential. In addition, it is an essential element needed at a high dose level. Therefore, it was considered unnecessary to require long-term and carcinogenicity studies with sulfur.

2.6. Reproductive toxicity

No reproductive toxicity studies were performed, as sulfur is generally regarded as safe for human exposure given the wide range of background exposure, its low acute and short-term toxicity and its non-genotoxic potential. In addition, it is an essential element needed at a high dose level. Therefore, it was considered unnecessary to require reproductive studies with sulfur.

2.7. Neurotoxicity

No studies were conducted. Sulfur does not belong to chemical groups known to induce neurotoxicity, no concern was raised from the other general studies, and therefore no study is required.

2.8. Further studies

No further studies were performed.

2.9. Medical data

The information on medical surveillance at a sulfur formulation site reported several cases of eye- and/or skin irritation, and several cases of malaise due to incidental exposure during handling. Chronic rhinitis, conjunctival irritation, cough, pharyngitis along with pruritus, headache and nausea are the most commonly reported signs and symptoms in workers, who are occupationally exposed to sulfur, either in mine workers or in people, who handle the pesticide or come into contact with foliage during field work.

2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD)

An ADI was not proposed by the rapporteur Member State given the wide range of background exposure, and considering that it is an essential element needed at a high dose level. It was reported in the DAR (B.7) that the average sulfur background intake value was 26 mg/kg bw/day [overall intake: 1.6 g/person/day, US National Academy of Medicine[4]]. During the PRAPeR 59 meeting of experts it was noted that it would be difficult to distinguish between exposure from background levels and from crop protection uses of sulfur. In addition, sulfur is generally regarded as safe for human exposure given its low acute and short-term toxicity and its non-genotoxic potential. For all these reasons, it was agreed not to propose an ADI, and nor an ARfD.

With regard to AOEL, the rapporteur Member State proposed in the DAR to use the 13-week rat study. Based on this, the proposed AOEL was 10 mg/kg bw/day, applying a safety factor of 100. During the PRAPeR 59 meeting of experts it was noted that for an essential element like sulfur, it was more appropriate to examine the human data available. It was agreed not to propose a systemic AOEL. It was noted that it would be difficult to set an upper threshold for the AOEL due to exposure via other sources and lack of information on intra-species variation. It was noted that operator exposure should be calculated and assessed against background level.

In conclusion, **it was agreed not to propose an ADI, AOEL and ARfD.**

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[4] Dietary Reference Intake for Water, Potassium, Sodium, Chloride and Sulfate. 2005. Institute of Medicine of the National Academies of Science. The National Academies Press; Washington, D.C.; www.nap.edu

2.11. Dermal absorption

No studies were performed with the representative formulations, sulfur 80% WG products and sulfur 98.5 % DP. A default value of 10 %, as the worst case based on the physical/chemical properties of sulfur, was proposed for all formulations.

2.12. Exposure to operators, workers and bystanders

The sulfur 80% WG products are water granule formulations containing 800 g/kg (80 % w/w) sulfur for use in grapes and cereals, at application rates of 2.56 and 8 kg sulfur/ha for grapes, and 4.8-6.4 kg sulfur/ha for cereals. Exposure calculations were performed at application rates of 2.56 and 6.4 kg sulfur/ha for grapes and cereals, respectively.

Sulphur 98.5 % DP (‘Sulphur Dust’) is a dustable powder formulation containing a nominal 985 g/kg (98.5 %) of sulfur for use in grapes, at the maximum application rate of 29.55 kg sulfur/ha as proposed by the applicants.

Operator exposure

Sulfur 80% WG products

Estimated systemic exposure (mg/kg bw/day) was performed according to calculations with the German and UK POEM model. The default for bodyweight of operator is 70 kg in the German model and 60 kg in the UK-POEM model. The treated area is 20 ha/day for the German model and 50 ha/day for the UK POEM.

		Total Systemic Exposure (mg/kg bw/day)	
		German Model	**UK POEM**
Cereals			
Vehicle mounted boom sprayer	No PPE	0.60	4.19
Grapes			
Vehicle mounted air blast sprayer	No PPE	0.40	No data in UK POEM
Hand-held application, high crops	No PPE	0.23	No data in UK POEM

Estimations of the potential operator exposure have been undertaken using the UK POEM and the German model. This indicated 0.6 mg/kg bw/day for cereals and 0.4 mg/kg bw/day for grapes for the German model, and 4.19 mg/kg bw/day for cereal for the UK POEM model. If the highest background intake value of 26 mg/kg bw/day [overall intake: 1.6 g/person/day, US National Academy of Medicine] was assumed, then the exposures calculated above would be negligible by comparison.

Sulfur 98.5 % DP.

The currently valid models (UK POEM and German model) cannot estimate the operator exposure to a powder plant protection product sprayed with a tractor mounted dust applicator. Consequently, field measurements should be provided. Thus, the exposure estimate for operators could not be assessed and a data gap was identified.

Bystander

Sulfur 80% WG products

For the estimation of bystander exposure, the rapporteur Member State used assumptions from Ganzelmeier *et al*.[5] The maximum bystander exposure was estimated to be 0.31 mg/kg bw/day, and therefore considered negligible compared to the background intake levels. During the meeting it was noted that some input parameters, like bodyweight of 50 kg, were applied. This was considered not fully correct, since generally a bodyweight of 60 kg is used. However, this was not considered to impact on the overall risk assessment.

Sulfur 98.5 % DP

The exposure estimate for bystander could not be assessed and therefore a data gap was identified.

Worker

Sulfur 80% WG products

To assess the re-entry exposure, the German generic re-entry exposure model has been used to provide an estimate of exposure during the conduct of re-entry work activities[6]. The maximum worker exposure was estimated to be 2.56 mg/kg bw/day, and therefore considered negligible compared to the background intake levels. Similarly to the bystanders, some input parameters, like transfer coefficient (TC) of 30000 cm^2/hour were applied. The meeting of experts considered that lower TC should have been considered for cereals. In any case, this was not considered to impact on the overall risk assessment.

Sulfur 98.5 % DP

The exposure estimate for worker could not be assessed and therefore a data gap was identified.

EFSA note after PRAPeR 59 meeting of experts: It should be noted that due to the low toxicological concern of sulfur (and as a consequence, the absence of an AOEL), the current assessment mainly represents an attempt to define exposure levels to sulfur.

3. Residues

Sulfur was discussed at the PRAPeR 60 meeting of experts on residues in October 2008 (round 12).

3.1. Nature and magnitude of residues in plant

Sulfur occurs abundantly in nature in different forms. Sulfur is essential for growth and physiological functioning of plants, but may also negatively affect plant metabolism (e.g. air-polluting sulfur gases). Against this background, extensive literature on function, uptake and

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[5] Ganzelmeier *et al*.: Studies on the spray drift of plant protection products. Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Berlin-Dahlem, Heft 305, 1995. Updated: BBA (2000:1). Bekanntmachung über Abdriftwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln harangezogen werden. Bundesanzeiger Nr. 100, 26 Mai 2000, 9879-9881

[6] Krebs B. *et al.*, (1998) Uniform Principles for Safeguarding the Health of Worker Re-entering Crop Growing Areas after Application of Plant Protection Products. (Bulletin of the German Plant Protection Service) Nachrichtenblatt des Deutschen Pflanzenschutzdienstes.10/98;Vol 50, Verlag Eugen Ulmer , Stuttgart, Germany

metabolism of sulfur compounds in plants exist. The assessment of the nature of residues presented in the DAR is mainly based on a review of public scientific literature.

3.1.1. Primary crops

Metabolism of elemental sulfur in the plant was studied following foliar application of [^{35}S]-labelled micronised sulfur to the surface of wheat leaves (10 mg [^{35}S]-sulfur/ leaf).

Individual leaves were sampled at different time intervals up to seven days after application and processed for analysis. Unincorporated sulfur was removed by surface washing previous to a solvent extraction of the leaf material. The rate of uptake by treated leaves was determined to be around 2 % of the applied [^{35}S]-labelled micronised sulfur.

Upon analysis of the leaf extracts, 13 radio-labelled compounds were separated, out of which sulfate, cysteine, cystine, methionine, and oxidised and reduced glutathion were identified. The unextractable fraction contained mainly proteins.

Of the extractable radioactivity (ERR), the amount incorporated in the pool of cysteine and cystine decreased from 35 % to 10 %, within 4 hours to 7 days after application. In contrary, the amount of [^{35}S]-sulfate increased from 10 % to 60 % of the ERR within the same period of time. No hydrogen sulfide was detected; however the authors could not exclude the hypothesis that the detected sulfate could originate from a secondary, fast oxidation of sulfide.

Based on the findings in wheat leaves, the authors proposed the metabolism of elemental sulfur applied to leaves of higher plants as follows: sulfur is not only incorporated into organic compounds, such as amino acids, peptides and proteins, but is also oxidised to sulfate. This oxidation of elemental sulfur to sulfate ions, directly or maybe through intermediate generation of sulfide, has been considered as a mechanism of detoxification.

Given the fact that the vast majority of the foliar applied elemental sulfur is not absorbed and metabolised by the plants, the rapporteur Member State has concluded that the pertinent residue on treated crops was elemental sulfur.

The mammalian toxicology assessment has concluded that sulfur is a substance of low toxicity, and it is not necessary to set an ADI or ARfD (refer to chapter 2.10). Therefore, the meeting of experts in residues agreed that a residue definition for consumer risk assessment has not to be proposed with respect to the use of elemental sulfur on crops. In the absence of an ADI and ARfD, an elaboration on residue levels in food in order to compare consumer exposure to those toxicological reference values, is not required.

However, for the sake of completeness, it should be noted that a number of residue trials, conducted in cereals and grapes with the representative formulations (WG and dust), were submitted by the applicants and evaluated in the DAR. In general, the trials determined the level of elemental sulfur on cereal grain and straw, and in grapes. In some more recent trials, also levels of total sulfur were quantified. Moreover, in processing studies elemental and total sulfur was analysed in grapes, must and wine. In the light of the decision of the expert meeting on toxicology not to set toxicological reference values, these data were however not peer reviewed.

3.1.2. Succeeding and rotational crops

The route of degradation of sulfur in soil was considered satisfactorily addressed by an open literature review. There is a natural cycle of oxidation and reduction reactions, which transform elemental sulfur into both organic and inorganic products (refer to chapter 4.1.1).

Plants absorb sulfur via the roots as sulfate ions (SO4 $^{2-}$), formed by chemical or microbial oxidation of elemental sulfur or other forms of sulfur in the soil. In the plant, sulfate is reduced to sulphide, and subsequently incorporated in various sulfur-containing organic molecules, including plant proteins. This is a naturally driven process, and therefore the use of elemental sulfur as a plant protection product is not deemed to lead to any relevant residues in rotational crops.

3.2. Nature and magnitude of residues in livestock

No studies were submitted that investigate the fate of sulfur in livestock.

In the DAR the rapporteur Member State has made reference to an evaluation report by the European Medicines Agency (EMEA) on elemental sulphur, used as therapeutic agent in food-producing animals. The report concluded that residues in animal tissues from sulfur administration could not be regarded as being of any concern, neither in terms of human health nor effects on micro-organisms used during processing of food stuffs.

With respect to the assessment of plant protection uses of sulfur in terms of consumer safety, elaboration on residue levels in food of animal origin is not required, since no ADI and ARfD were set for sulfur.

3.3. Consumer risk assessment

A consumer risk assessment is neither possible nor necessary, as the mammalian toxicology assessment has concluded that sulfur is of low toxicity, and it is not necessary to set an ADI or ARfD (refer to chapter 2.10).

It should, however, be noted that there is reasonably sufficient data and information available that could be used to estimate consumer and livestock exposure to residues originating from the use of elemental sulfur as a plant protection product in cereals and grapes, though not all of these data and information were further reviewed, when the PRAPeR 59 meeting of experts came up with the decision not to set toxicological reference values.

In the DAR the rapporteur Member State has estimated consumer exposure of elemental sulfur linked to the notified uses in cereals and grapes with different intake models. The rapporteur Member State also tried to estimate total sulfur intakes from food and water to evaluate general exposure. However, the PRAPeR 60 meeting of experts did not consider these estimates (not peer reviewed), but concluded that no dietary risk assessment needs to be carried out, since toxicological reference values were not set for sulfur.

3.4. Proposed MRLs

The meeting of experts did not propose a residue definition for monitoring and an MRL for elemental sulfur. It was suggested that sulfur was a candidate to be placed in Annex IV of Council Regulation (EC) No 369/2005[7]

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[7] 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

4. Environmental fate and behaviour

Sulfur was discussed at the PRAPeR 57 meeting of experts on fate and behaviour into the environment in October 2008, on the basis of the DAR (August 2007), corrigendum I (August 2008) and corrigendum II (December 2008).

Elemental sulfur occurs abundantly in nature, and it is constantly exposed to all the three environmental compartments (soil, water, air). It is stable under sterile conditions, but readily undergoes degradation through oxidative or reductive processes under aerobic or anaerobic conditions by specific microbial organisms to sulfate ions (SO_4^{2-}) or sulfites (-S-), respectively, both of which in turn are abundant in nature.

4.1. Fate and behaviour in soil

4.1.1. Route of degradation in soil

Sulfur is a component of the environment, and there is a natural cycle of oxidation and reduction reactions, which transforms sulfur into both organic and inorganic products. A description of the environmental fate and behaviour of sulfur in soil, based on literature review, was provided by the applicants and summarised in the DAR. This general introduction provided an overview of the processes (chemical and biological transformation, oxidation-reduction) that govern the behaviour of naturally occurring sulfur in the environment, in view of the fact that these processes will also govern the fate of sulfur added as a fungicide to the same environment. Elemental sulfur is known to enter the sulfur cycle immediately after application, i.e. elemental sulfur is transformed by micro-organisms into various stages of oxidation (e.g. sulfate and sulfite), which are soluble and thus made available for uptake by plants and animals. This is an active uptake process, since sulfur is an essential element required for maintaining crucial life functions.

It was concluded that as long as sulfur cycle is well known and documented, the route of degradation of sulfur in soil, described by this literature review, was satisfactorily addressed and no further study is necessary.

Justifications for non-submission of photodegradation study in soil was provided by the applicants and summarised in corrigendum I. The Member State experts considered that this was adequate, and it was agreed that it was not necessary to require data to address the soil photolysis of sulfur.

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

A preliminary remark should be considered on the assessment of persistence of sulfur in soil. The rate of *oxidation* of elemental sulfur is the process that determines the rate, at which sulfate is available to plants. Oxidation is preceded by a short incubation period allowing the formulated granules to absorb moisture from the soil, and then disintegrate to release sulfur. Oxidation then proceeds quickly and smoothly, the kinetics being a function of temperature, soil pH, organic content of soil, and particle size of elemental sulfur.

The submitted studies on persistence of sulfur in soil were published studies. Due to the absence of raw data, the rapporteur Member State could not validate the studies, but considered them supportive to describe the behaviour of sulfur in the environment, as well as conditions (pH, temperature,…), that influenced sulfur fate. It has been shown that the oxidation rate of sulfur increases with the particle size of the elemental sulfur used, and with temperature. The view of the Member State experts was that because of the complexity of the processes governing the oxidation rate of elemental sulfur and some deficiencies in the laboratory studies, including the lack of information on the method of calculation of the oxidation rates, the results of these studies should not be used quantitatively (i.e. derived “DT_{50}”) in the exposure assessment. It was also agreed that taking into account the natural background concentration of sulfur in the top 15 cm layer of agricultural soils of 50-1000 mg S/kg soil, reliable “DT_{50}” values for elemental sulfur are not necessary to finalise the assessment.

Sulfur is not expected to be persistent in elemental form, and therefore no accumulation of elemental sulfur is anticipated.

In the original DAR, initial and time weighted average PEC (predicted environmental concentrations) of elemental sulfur in soil were calculated for grapes (8.0 kg a.s./ha applied up to eight times with the spray interval of minimum 7 days), barley (6.4 kg a.s./ha applied twice with the spray interval of 14 days), and wheat (4.8 kg a.s./ha applied twice with the spray interval of 14 days). The peer review agreed that the initial maximum PEC soil values based on the maximum annual total dose for the two formulations should be used for the risk assessment for terrestrial organisms. New calculations were provided and evaluated in corrigendum II. While the PEC values are not peer reviewed, the EFSA supports the assessment made by the rapporteur Member State, as the appropriate assumptions were considered in the calculations, with the exception of PECsoil calculated for the “sulfur dust” formulation, where the rapporteur Member State used GAPs (30+30+25+20+20 kg/ha) issued from the document MIIIA1Sec5_01 provided by the applicants. As these GAPs do not correspond to the ones provided in the original representative uses applied for (as defined in the table “Summary of representative uses evaluated”), the new values cannot be considered valid. The EFSA re-calculated PECsoil values for the “sulfur dust” formulation, taking into consideration a maximum application dose of 29.55 kg a.s./ha and five applications per year, which corresponds to a maximum annual total dose of 147.75 kg a.s./ha/year. Assuming an average crop interception of 70 % for the five applications on grapes, the total amount of sulfur applied is 44.325 kg a.s./ha/year. The resulting initial $PEC_{soil,\ maximum}$ value is included in Appendix A.

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

Elemental sulfur is not adsorbed to soil surfaces by the normal electrostatic forces common to other chemical pesticides. However, the oxidation product (sulfate, SO_4^{2-}) can interact with soil surfaces by anion adsorption. The movement of sulfate is influenced by anion exchange capacity, solution sulfate concentration, pH, competition with other anions, notably phosphate, calcium addition (co-precipitation) and moisture content.

A study for the determination of sulfur adsorption to soil was submitted by the applicant. As long as this study was not valid due to technical problems, the rapporteur Member State used a number of available equations in order to determine the most conservative K_{om} and K_{oc}, estimated from K_{ow} and water solubility. This led to a K_{oc} value of 1949.8 mL/g.

A lysimeter study was available, where a sandy loam soil was treated with bentonite/elemental sulfur mixture, micronized elemental sulfur, and ammonium sulfate applied in the solid form to the soil surface at 50 kg/ha. Additionally, atmospheric deposition of sulfur varied between 6.7-7.8 kg a.s./ha/year. The average annual rainfall for the three years was 615 mm. Results indicated that sulfate was highly mobile and prone to leaching under the experimental conditions, whereas the slow release characteristics of elemental sulfur led to smaller leaching losses.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

Sulfur is slightly soluble in water (maximum determined water solubility: 63 µg/L). A laboratory study was conducted with sulfur dissolved in organic solvents, which were evaporated before exposure to light for 24 hours. As long as sulfur is insoluble in water, the study was considered acceptable to assess direct photolysis and does not presume sulfur degradation rate by photolysis in water.

Ready biodegradation studies are not relevant for inorganic compounds, such as sulfur. Sulfur is therefore considered as non ready biodegradable.

Justifications for not providing water/sediment studies were presented by the applicants and considered acceptable by the peer review.

Taking into consideration that sulfur, when entering an aquatic system, is expected to preferentially adsorb to sediment and then be oxidised, the rapporteur Member State questioned in the DAR, if a water/sediment study would be necessary for a better understanding of the behaviour and oxidation rate of sulfur in the sediment system. The view of the Member State experts was that the cycle of sulfur in the environment is well understood, and consequently it was agreed that it was not necessary to require data to address the route and rate of degradation of sulfur in natural aquatic systems.

Originally, the aquatic exposure assessment was provided by the applicants based on FOCUS surface water calculations. The Member State experts agreed with the rapporteur Member State that the use of FOCUS modelling is not appropriate for inorganic compounds, and supported the RMS's approach to address the risk assessment to aquatic organisms taking into account an absence of effects to organisms at the highest water solubility limit of sulfur (see section 5.2). However, as no studies on benthic organisms were available, the experts on fate and behaviour concluded that a worst case assessment for the sediment compartment can be performed based on the partition properties of sulfur, the maximum total annual dose for the two formulations, and taking into account the percentage values for drift and run-off/drainage entry routes as prescribed by FOCUS Step 2. The new calculations were provided by the rapporteur Member State on p. 525 of the corrigendum II (December 2008). The input value for the runoff/drainage contribution into surface water is not in agreement with the FOCUS Step 2 recommendations (only 0.5 % of runoff from soil to surface water was considered in place of the agreed 4 % for South Europe), and the input into surface water via spray drift was not mentioned. Additionally, for the "sulfur dust" formulation, the GAPs used did not correspond to the ones provided in the original representative uses applied for (see section 4.1.2). Therefore, the new PECsed values provided by the rapporteur Member State after the PRAPeR 57 meeting of experts cannot be considered valid, and the EFSA identified a data gap for an exposure assessment for the sediment compartment.

4.2.2. Potential for ground water contamination of the active substance, their metabolites, degradation or reaction products

The Member State experts agreed that sulfur is not of concern for the contamination of groundwater, but that the potential for groundwater contamination for sulfates needed to be addressed, as they are highly mobile in soil. The aim of PECgw determination for sulfates was to assess their concentrations against the drinking water limit of 250 mg/L set in the Drinking Water Directive 98/83/CE[8]. The rapporteur Member State's estimation was based on

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[8] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

a worst case assumption that 100 % of sulfur applied to soil is oxidised to sulfates (SO_4^{2-}), and 100 % of sulfates will leach to groundwater. The water volume percolated at 1 m depth determined in each FOCUS scenario for vines was considered. The total amount of sulfur applied to soil, and the equivalence in SO_4^{2-}(1 S_8 giving 8 SO_4^{2-}) were determined for a period of 26 years, based on an application rate of 30 kg S/ha (sulfur dust applied on grapes), five times a year, with 85 % foliar interception. Results (maximum PECgw value of 81.4 mg SO_4^{2-}/L estimated for Sevilla scenario) indicated that the potential for groundwater contamination from sulfates above the drinking water limit of 250 mg/L from the applied for intended uses is low.

It was concluded that the evaluation provided in the DAR was adequate and sufficient to complete a groundwater exposure assessment at EU level for the applied for intended uses.

4.3. Fate and behaviour in air

The vapour pressure of sulfur was determined as 9.8 x 10^{-5} Pa at 20ºC. It is therefore non volatile, even if its Henry's law constant was determined at 0.05 Pa m^3/mol, which is due to its very low water solubility. Sulfur is therefore not expected to transfer to the air compartment.

5. Ecotoxicology

Sulfur was discussed at the PRAPeR 58 meeting of experts for ecotoxicology in October 2008. Data sets were submitted by two applicants (Sulfur Working Group and Sulfur Task Force). Thirteen representative uses as a fungicide were included in the GAP tables. The representative uses were grouped by the rapporteur Member State in the uses in cereals and vineyards. The risk assessment was conducted for the uses in cereals of 2 x 4.8 and 2 x 6.4 kg a.s./ha (sulfur 80% WG) and for the uses in vineyards of 8 x 2.56 kg a.s./ha, 8 x 8 kg a.s./ha (sulfur 80% WG) and 5 x 19.7 and 5 x 29.55 kg a.s./ha (sulfur dust).

The risk assessment was conducted according to the following guidance documents: Risk Assessment for Birds and Mammals. SANCO/4145/2000 September 2002; Aquatic Ecotoxicology, SANCO/3268/2001 rev.4 final, October 2002; Terrestrial Ecotoxicology, SANCO/10329/2002 rev.2 final, October 2002; Risk Assessment for non-target arthropods, ESCORT 2, March 2000, SETAC.

In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, new studies could not be considered in the peer review.

5.1. Risk to terrestrial vertebrates

The acute and short-term toxicity of sulfur to birds is low with LD_{50} values of >2000 mg a.s./kg bw and >1335 mg a.s./kg bw/day. No long-term toxicity study with birds or mammals was conducted. The rapporteur Member State considered the long-term risk to birds and mammals as low because of the low acute and short-term toxicity, and because no long-term toxicity studies were required for the toxicology assessment. It was further mentioned that sulfur has a long history of use and is also used in pharmaceuticals for long-term medication. The experts agreed in principle that long-term studies can be waived, but it was suggested that the waiver needs to be supported by a more detailed and comprehensive argumentation/information. It was noted during the expert meeting that there is evidence from published literature that uptake of sulfates can lead to brain pathologies (polioencephalomalacia) in ruminants, where the sulfate is reduced to sulfide in the rumen. A position paper on this topic was submitted by Sweden after the PRAPeR 58 meeting of experts. The experts agreed in the meeting to set a data gap for the applicant to submit further and more detailed information to support the assumption of low long-term risk to birds and mammals.

The first-tier acute and short-term TERs for insectivorous birds in cereals were >7.7 and >9.22 for the application rate of 2 x 4.8 kg a.s./ha, and >5.78 and >6.91 for the application rate of 2 x 6.4 kg a.s./ha. The suggested refinement of PT was not agreed by the experts, since it was not sufficiently supported by data. The refinement based on residues on small and large insects was agreed in principle. However, the suggested proportion of consumption of large and small insects was not sufficiently supported by data. Therefore, it was suggested to calculate the TERs based on the consumption of only large or small insects. The TERs were recalculated in the corrigendum from November 2008. The acute TERs for birds consuming large insects were however recalculated by EFSA after the peer-review, based on the correct standard RUD value of 14 for large insects. The resulting refined acute TER based on a diet of large insects was above the Annex VI trigger (TER >34.2). The TER based on a diet of small insects was, however, still below the Annex VI trigger of 10, but close to the trigger for the application rate of 2 x 4.6 kg a.s./ha (TER >9.21). Since the TERs are “greater than” values, the acute risk was considered as low. The refined short-term TERs were above the Annex VI trigger of 10 for both diets for the lower application rate. For the application rate of 6.4 kg a.s./ha, only the acute and shot-term TER from consumption of large insects exceeded the trigger of 10. The acute and short-term risk to insectivorous birds needs further refinement for the application rate of 2 x 6.4 kg a.s./ha.

The applied for intended uses suggest that sulfur can be applied at early and late growth stages of cereals. Therefore, it was suggested by the experts that also the risk to herbivorous birds (early growth stages) should be assessed. The first-tier TERs were presented in addendum 2 to the DAR from November 2008. The acute and short-term TER values were >5.56 and >9.04 for the application rate of 2 x 4.6 kg a.s./ha, and >4.17 and >6.8 for the application rate of 2 x 6.4 kg a.s./ha. Therefore, a data gap was proposed by the rapporteur Member State for further refinement of the risk assessment for herbivorous birds, or to restrict the application to late growth stages. This proposal is agreed by EFSA.

The first-tier acute and short-term TERs for insectivorous birds exceeded the Annex VI trigger of 10 for the use in vineyards, at an application rate of 2.56 kg a.s./ha (calculated by EFSA and included in the list of endpoints). The acute and short-term TERs were below the Annex VI trigger of 10 for the uses in vineyards for application rates of 8 kg a.s./ha and more. The refined risk assessment was based on great tit (*Parus major*) as a focal species and PD (proportion of different food items). The proposed refinement was not accepted by the experts, since no supporting data/information were provided. New information was submitted by the applicants, but could not be considered in the peer-review in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No 1095/2007. Therefore, a data gap remains to address further the risk to insectivorous birds for the uses in vineyards with application rates of 8, 19.7 and 29.5 kg a.s./ha.

The acute toxicity of sulfur to mammals was low with LD_{50} values for rat ranging from >1760 to >5000 mg a.s./kg bw. The highest LD_{50} value of >5000 mg a.s./kg bw was used in the risk assessment, since no mortality was observed in the studies. The first-tier acute TERs exceeded the Annex VI trigger of 10 for the uses in cereals (insectivorous mammals). A multiple application factor of 2 and a deposition factor of 0.5 were taken into account in the TER calculations for herbivorous mammals in vineyards. The trigger was exceeded for an application rate of 8 x 2.56 kg a.s./ha, but not for the application rates of 8 x 8, 5 x 19.7 and 5 x 29.5 kg a.s./ha. A new refined risk assessment was submitted by the applicants and included in the corrigendum from August 2008, but could not be considered in the peer-review in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No 1095/2007. A data gap remains for further refinement of the risk assessment for herbivorous mammals in vineyards for application rates of 8 x 8, 5 x 19.7 and 5 x 29.5 kg a.s./ha.

The risk to birds and mammals from secondary poisoning and uptake of contaminated drinking water was assessed as low.

Overall, it was concluded that the acute and short-term risk to insectivorous birds was low for the representative use in cereals and vineyards, at application rates of 2 x 4.6 kg a.s./ha and 8 x 2.56 kg a.s./ha, respectively. The risk to herbivorous birds needs further refinement for the uses in cereals. The risk to insectivorous birds needs to be refined further for the uses in cereals at an application rate of 2 x 6.4 kg a.s./ha, and for the uses in vineyards at application rates of 8, 19.7 and 29.5 kg a.s./ha. The risk to mammals was assessed as low for the use in cereals and the use in vineyards at an application rate of 8 x 2.56 kg a.s./ha. Further refinement of the risk assessment is needed for application rates of 8 x 8, 5 x 19.7 and 5 x 29.5 kg a.s./ha. Some uncertainty remains with regard to the long-term risk to birds and mammals.

5.2. Risk to aquatic organisms

The endpoints observed in the tests with aquatic organisms were above the solubility limit of sulfur (> 0.063 mg a.s./L). No adverse long-term effects were observed in the studies with fish (NOEC >63 mg a.s./L). The long-term studies with daphnids were assessed as not valid, and a data gap was identified. The rapporteur Member State indicated that a new chronic study with daphnids is currently ongoing. Adverse effects were observed on algae growth. However, those effects were considered to be due to light inhibition from continuously resuspended sulfur particles (shaking of test vessels). The solubility limit was proposed as endpoints for all studies with aquatic organisms.

Sulfur entering surface water is expected to adsorb to sediment. No studies with sediment-dwelling organisms were available. Therefore, a data gap was identified by the rapporteur Member State to address the long-term risk to sediment-dwelling organisms. The experts agreed to the data gap proposed by the rapporteur Member State.

The applicability of FOCUS calculations was questioned by the rapporteur Member State, since the FOCUS calculations were developed for organic compounds and no TER calculations were performed. The risk to aquatic organisms in the water column was considered in general as low, because the solubility of sulfur in water is very low, and no effects were observed at concentrations, which exceeded the water solubility by several orders of magnitude. The risk of bioconcentration was considered to be low. Uncertainty remains with regard to the risk to sediment-dwelling organisms, and a study with *Chironomus riparius* was considered necessary.

5.3. Risk to bees

Acute oral and contact toxicity studies were conducted. No adverse effects were observed up to the highest tested dose of 100 µg a.s./bee. The HQ values were calculated as <184.5 to <276.7 for the uses of sulfur dust in grapes. For the use of sulfur 80% WG products, the HQ values were <48 and <64 (cereals), <25.6 and <80 (grapes). Also, the off-field HQ values were calculated for the grape uses. The HQ values were less than 50 at a distance of 3 meters from the field (8.02 % drift).

In the PRAPeR 58 meeting of experts it was agreed that the risk to bees was low for the uses in cereals. The rapporteur Member State suggested that the risk to bees in grapevines would be low also for the higher application rates than 2.56 kg a.s./ha, since grapevine is not an attractive foraging plant for bees, and the HQ values were below the Annex VI trigger of 50 for exposure in the off-field area. It was noted during the peer-review that information was available in one Member State that bees also forage in vineyards. The experts agreed that the risk to bees is likely to be low, since no mortality was observed at the highest tested concentrations, and the endpoints are NOECs instead of LD_{50}s. However, some experts were of the opinion that the risk to bees from the sulfur dust uses should be addressed further at Member State level.

5.4. Risk to other arthropod species

Standard laboratory tests were conducted with the indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. The off-field HQ values were below the Annex VI trigger of 2 for both species for the uses in cereals (sulfur 80 % WG products). The in-field HQ values were 29.6 and 39.5 for *A. rhopalosiphi* indicating a potential high in-field risk to parasitic hymenoptera. The in-field and off-field HQs for *A. rhopalosiphi* were above the Annex VI trigger of 2 for all uses in vineyards (except the off-field HQ of 1.27 for the lowest use rate of 2.56 kg a.s./ha). *T. pyri* reacted less sensitive to sulfur with off-field HQs of <2. The in-field HQs were >2 for *T. pyri,* except for the lowest application rate of 2.56 kg a.s./ha. In-field no spray buffer zones of 10 m and 15 m were required to achieve off-field HQs of less than 2 for the standard indicator species.

Additional laboratory studies were conducted with *Chrysoperla carnea*, *Poecilus cupreus* and *Aleochara bilineata*. In the studies with the sulfur 80 % WG products, no significant effects were observed at an application rate of 10 kg a.s./ha. *C. carnea* reacted more sensitively in a test with sulfur dust, where 50 % mortality was observed in the extended laboratory study at an application rate of 2.5 kg a.s./ha, but no effects were observed in the test with *P. cupreus* at a rate of 90 kg a.s./ha. The risk to *A. bilineata, P. cupreus* and to *C. carnea* was considered to be low for the uses in cereals. The risk to the leaf-dwelling predator *C. carnea* was assessed as low for the use of sulfur 80 % WG products in vineyards at the rate of 2.56 kg a.s./ha. For the uses of sulfur dust in vineyards it was not demonstrated that the in-field risk is low for *C. carnea*. The risk to the soil surface-dwelling species *P. cupreus* was assessed as low up to the highest application rates in vineyards, and for *A. bilineata* up to an application rate of 2.5 kg a.s./ha.

The most sensitive species tested was the parasitoid *Trichogramma cacoeciae*, for which 100 % mortality was observed at an application rate of 0.812 kg a.s./ha in an extended laboratory study. Reproduction was reduced by 34 % at an application rate of 0.0008 kg a.s./ha. Adverse effects did not exceed the Annex VI trigger of 50 % up to a rate of 0.05 kg a.s./ha. Those application rates were several orders of magnitude lower than the in-field exposure rates of 7.68 – 88.5 kg a.s./ha (in-field), and in the same range or less than the off-field exposure rates of 0.0399 – 0.7098 kg a.s./ha, indicating a potential high risk to sensitive parasitoids for all applied for intended uses. The rapporteur Member State indicated that the applicant has initiated an aged residues test with *T. cacoeciae*.

Field studies were conducted to investigate potential adverse effects on predatory mites in vineyards. Only short-term effects of up to 40 % were observed at application rates of 2.56 kg a.s./ha (sulfur 80% WG), confirming that the risk to predatory mites is low for application rates of up to 2.56 kg a.s./ha. Two studies with predatory mites were conducted with sulfur dust, at application rates of 2 x 30 kg product/ha, 1 x 25 kg product/ha and 2 x 20 kg product/ha. In one study no significant effect was observed, and in the second study recolonisation/recovery was observed to take place within two months after the last application. It was concluded that the studies show that the risk to predatory mites is low for the uses of sulfur dust in vineyards at application rates of 5 x 19.7 kg a.s./ha, and that it gives also some indication that the risk is low for the application rates of 5 x 29.5 kg a.s./ha, although not all five applications in the field study were conducted at the highest recommended rate.

Overall, it was concluded that it was not demonstrated in the available risk assessment that the risk to sensitive non-target arthropods (parasitoids) was low. Further higher tier testing, e.g. field studies or aged residues tests are required to provide evidence that recolonisation of the in-field area by sensitive hymenoptera is possible within 1 year. The experts agreed on a data gap for the applicants to demonstrate that recovey/recolonisation of the in-field area are possible for sensitive parasitoid species.

5.5. Risk to earthworms

The acute toxicity of sulfur to earthworms was low. No significant adverse effects were observed up to the highest tested concentrations of 1576 mg a.s./kg soil (sulfur 80 % WG products), and 985 mg a.s./kg soil (Sulphur Dust). The TER values were in the range of 16.7 – 123 indicating a low risk to earthworms from the representative uses evaluated.

5.6. Risk to other soil non-target macro-organisms

It was discussed, if studies with other soil-dwelling non-target arthropods should be required, since the in-field HQ values for the indicator non-target species *A. rhopalosiphi* was >2. The rapporteur Member State suggested that no studies were needed, since the risk to earthworms and to soil non-target micro-organisms was assessed as low. The experts agreed that no further studies were required, considering also that no effects were observed in the studies with soil surface-dwelling arthropods, at application rates of up to 10 kg a.s./ha and 90 kg a.s./ha.

5.7. Risk to soil non-target micro-organisms

No effects of >25 % on soil respiration and nitrification were observed at concentrations of up to 400 mg product/kg soil (corresponding to 10 times the maximum application rate of 30 kg a.s./ha). Therefore, the risk to soil non-target micro-organisms was considered to be low for the representative uses evaluated.

6. Residue definitions

6.1. Soil

Definition for risk assessment: sulfur

Definition for monitoring: none

6.2. Water

6.2.1. Ground water

Definition for exposure assessment: sulfur and sulfates

Definition for monitoring: none

6.2.2. Surface water

Definition for risk assessment
in surface water: sulfur
in sediment: sulfur

Definition for monitoring: none

6.3. Air

Definition for risk assessment: sulfur

Definition for monitoring: none

6.4. Food of plant origin

Definition for risk assessment: none required as no ADI and ARfD were set

Definition for monitoring: none proposed

6.5. Food of animal origin

Definition for risk assessment: none required as no ADI and ARfD were set

Definition for monitoring: none proposed

6.6. Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

6.6.1. Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
sulfur	The available information only enables a qualitative assessment on the oxidation rates of sulfur. No data required.	The risk to earthworms and soil micro-organisms was assessed as low.

6.6.2. Ground water

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg/L 1m depth for the representative uses** (at least one FOCUS scenario or relevant lysimeter)	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
sulfur	Low mobile (Koc derived from water solubility = 1950 mL/g)	No data available, not required	Yes	No	No effects on aquatic organisms at the level of solubility.
sulfates	No data available, not required	No* (estimated max PECgw = 81.4 mg SO_4^{2-} based on a worst case assumption that 100 % of sulfur applied to soil is oxidised to sulfates, and 100 % of sulfates will leach to groundwater; see section 4.2.2)	No data submitted. No data needed.	No	No data submitted. No data needed.

* based on the drinking water limit of 250 mg/L set in the Drinking Water Directive 98/83/EC.

6.6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
sulfur	No effects on aquatic organisms at the level of solubility in water. Uncertainty remains with regard to the risk to sediment-dwelling organisms (data gap)

6.6.4. Air

Compound (name and/or code)	**Toxicology**
sulfur	Rat LC_{50} inhalation > 5.43 mg/L air over 4 hours. – No classification proposed.

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- 5-batch data for all members of the Sulfur Working Group except CITIS (relevant for all uses evaluated, data gap identified by the PRAPeR 56 meeting of experts in October 2008, proposed submission date unknown, refer to chapter 1).
- 5-batch data for the Sulfur Task Force for the mined sulphur sources Quimetal and Zaklady (relevant for all uses evaluated, data gap identified by the PRAPeR 56 meeting of experts in October 2008, proposed submission date unknown, refer to chapter 1).
- Details of starting materials (including catalysts) and methods of manufacture for all members of the Sulfur Working Group and the Sulfur Task Force (relevant for all uses evaluated, data gap identified by the PRAPeR 56 meeting of experts in October 2008, proposed submission date unknown, refer to chapter 1).
- For ‘Sulphur Dust’ dry sieve test and flowability should be conducted before and after accelerated storage to show compliance with the FAO specification (relevant for all uses evaluated, data gap identified by the PRAPeR 56 meeting of experts in October 2008, proposed submission date unknown, refer to chapter 1).
- For ‘Sulphur 80 WG’ suspensibility at the highest and lowest in use concentrations, nominal size range of the granules using CIPAC MT 170 and attrition resistance (relevant for all uses evaluated, data gap identified by the PRAPeR 56 meeting of experts in October 2008, proposed submission date unknown, refer to chapter 1).
- For ‘Microthiol Disperss’ suspensibility before and after accelerated storage and 2 years shelf-life study (relevant for all uses evaluated, data gap identified by the PRAPeR 56 meeting of experts in October 2008, proposed submission date unknown, refer to chapter 1).
- For ‘Kumulus WG’ explosive properties (shock and friction), oxidising properties, accelerated and shelf-life storage studies, spontaneity of dispersion and attrition resistance (relevant for all uses evaluated, data gap identified by the PRAPeR 56 meeting of experts in October 2008, proposed submission date unknown, refer to chapter 1).
- For ‘Netzschwefel Stulln’ accelerated and shelf-life storage studies, attrition and suspensibility at the highest and lowest in use concentrations (relevant for all uses evaluated, data gap identified by the PRAPeR 56 meeting of experts in October 2008, proposed submission date unknown, refer to chapter 1).
- Operator, worker and bystander exposure estimate to sulfur 98.5 % DP formulation (relevant for use in grapes; data gap identified in the DAR and confirmed by the PRAPeR 59 meeting of experts in October 2008, proposed submission date unknown; refer to point 2.12).
- Predicted environmental concentrations calculations for the aquatic sediment compartment (PECsed) (relevant for all uses evaluated, data gap identified by EFSA after the PRAPeR 57 meeting of experts, proposed submission date unknown, refer to point 4.2.1).
- Further and more detailed information is required to support the assumption of low long-term risk to birds and mammals (relevant for all representative uses evaluated;

data gap identified at the PRAPeR 58 meeting of experts on ecotoxicology in October 2008; no submission date proposed by the notifier; refer to point 5.1)

- The risk to insectivorous birds needs further refinement (relevant for the uses in cereals at application rates of 4.8 and 6.4 kg a.s./ha, and for the uses in grapes at application rates of 8, 19.7 and 29.5 kg a.s./ha; data gap identified in the PRAPeR 58 meeting of experts on ecotoxicology in October 2008; new information was submitted by the applicants and included in an addendum, but not considered in the peer-review in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No 1095/2007; refer to point 5.1)
- The risk to herbivorous birds needs refinement for the uses in cereals (relevant for the uses in cereals at early growth stages, the data gap would become obsolete if the uses in cereals are restricted to late growth stages; data gap identified by the rapporteur Member State after the PRAPeR 58 meeting of experts and confirmed by EFSA; no submission date proposed by the applicant; refer to point 5.1)
- The risk to herbivorous mammals needs refinement (relevant for the uses in vineyards at application rates of 8, 19.7 and 29.5 kg a.s./ha; data gap identified at the PRAPeR 58 meeting of experts on ecotoxicology in October 2008; a new refined risk assessment was submitted by the applicants and included in a corrigendum, but not considered in the peer-review in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No 1095/2007; refer to point 5.1)
- A valid long-term study with daphnids (relevant for all representative uses evaluated; data gap identified at the PRAPeR 58 meeting of experts on ecotoxicology in October 2008; the rapporteur Member State indicated during the expert meeting that the study was initiated by the applicants; refer to point 5.2)
- A study with sediment-dwelling organisms (*Chironomus riparius*) (relevant for all representative uses; data gap identified by the rapporteur Member State and agreed at the PRAPeR 58 meeting of experts on ecotoxicology in October 2008; no submission date proposed by the applicants; refer to point 5.2)
- Recovery/recolonisation of the in-field area needs to be demonstrated for sensitive parasitoid species (relevant for all representative uses; data gap identified by the rapporteur Member State and agreed at the PRAPeR 58 meeting of experts on ecotoxicology in October 2008; refer to point 5.4)

CONCLUSIONS AND RECOMMENDATIONS

OVERALL CONCLUSIONS

This conclusion was reached on the basis of the evaluation of the representative uses as a fungicide on cereals and grapes. Sulfur is also known to have acaricidal properties. Full details of the GAP can be found in the endpoints.

The representative formulated products for the evaluation were 'Thiovit Jet 80 WG', 'Microthiol Disperss', 'Kumulus WG', 'Netzschwefel Stulln' and 'Sulphur 80 WG' water dispersible granule formulations (WG) and 'Sulphur Dust' a dustable powder formulation (DP).

Monitoring methods are not required see sections 3, 4 and 5.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection products are possible. Some physical and chemical properties are missing, and some of the sources need 5-batch data.

Sulfur is generally regarded as safe for human exposure given the wide range of background exposure, since it is naturally present and abundant in food, where it can be found in the form of sulfate, free amino acids, proteins and vitamins, and it is an essential element needed at a high dose level. Toxicological studies showed that sulfur has a low acute oral, dermal and inhalation toxicity. It is a skin irritant but not an eye irritant, nor a skin sensitizer. The following classification was proposed: **Xi, R38 "Irritating to the skin"**. Sulfur has also a low short-term oral toxicity, since the NOAEL in a 28-day and 90-day rat study was the highest dose level tested (1000 mg/kg bw/day). The weight of evidence indicates that sulfur is not a genotoxic agent. Thus, since sulfur is an essential element, and considering its wide range of background exposure, its low acute and short-term toxicity and its lack of genotoxic potential, long-term toxicity-, carcinogenicity- and reproductive toxicity studies were not performed, nor they were required. Likewise, it was agreed not to propose an ADI, AOEL and ARfD. Operator, bystander and worker exposure to sulfur 80% WG products was considered negligible compared to the wide range of background level.

Residues do not need to be considered, as the mammalian toxicology assessment has concluded that sulfur is of low toxicity, and it is not necessary to set an ADI or ARfD. Therefore, a consumer risk assessment is neither possible nor necessary.

Most of the data on the environmental fate and behaviour of sulfur in soil, water and air are derived from open literature. However, the available information is considered sufficient to complete an environmental exposure assessment at EU level for the applied for intended uses, with the exception of the sediment compartment. The potential for groundwater contamination by sulfates (the main oxidation product of sulfur in soil) above a toxicologically based concentration limit of 250 mg/L, was assessed as low.

The risk to herbivorous birds needs further refinement for the uses in cereals (early application). The risk to insectivorous birds needs to be refined further for the uses in cereals at an application rate of 2 x 6.4 kg a.s./ha, and for the uses in vineyards at application rates of 8, 19.7 and 29.5 kg a.s./ha. Further refinement of the risk assessment for herbivorous mammals is needed, at application rates in vineyards of 8 x 8, 5 x 19.7 and 5 x 29.5 kg a.s./ha. The remaining uncertainty with regard to the long-term risk to birds and mammals needs to be addressed further. The risk to aquatic organisms in the water column was considered in general as low, because the solubility of sulfur in water is very low, and no effects were observed at concentrations, which exceeded the water solubility by several orders of magnitude. A study with *Chironomus riparius* was considered necessary to address the risk to sediment-dwelling organisms.

The HQ values for bees indicated a low risk to bees for the uses in cereals and in vineyards at an application rate of 2.56 kg a.s./ha. The HQ values exceeded the Annex VI trigger of 50 for all other uses in vineyards. The experts considered the risk to bees likely to be low, because no mortality of bees was observed at the highest tested doses. It was suggested in the meeting that the uncertainty with regard to the risk to bees from application rates of 8, 19.7 and 29.5

kg a.s./ha in vineyards should be addressed further at Member State level, considering also risk mitigation measures.

The risk to sensitive non-target arthropods (parasitoids) was not demonstrated to be low in the available risk assessment. Further higher tier testing, e.g. field studies or aged residues tests are required to provide evidence that recolonisation of the in-field area by sensitive hymenoptera is possible within 1 year.

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

None.

CRITICAL AREAS OF CONCERN

- The aquatic exposure assessment (sediment compartment only) needs to be addressed.
- The risk to herbivorus birds needs further refinement for early applications in cereals.
- The risk to insectivorous birds needs further refinement for the use in cereals at an application rate of 2 x 6.4 kg a.s./ha, and for the uses in vineyards at application rates of 8, 19.7 and 29.5 kg a.s./ha.
- The risk to herbivorous mammals needs further refinement for the uses in vineyards at application rates of 8, 19.7 and 29.5 kg a.s./ha.
- A risk assessment for sediment-dwelling organisms needs to be conducted.
- The risk to sensitive non-target arthropods needs further refinement.

APPENDICES

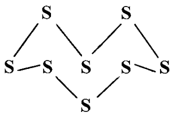
APPENDIX A – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Sulfur (E-ISO, JMAF, ESA)
Function (*e.g.* fungicide)	Fungicide, acaricide

Rapporteur Member State	France
Co-rapporteur Member State	/

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Sulfur
Chemical name (CA) ‡	Sulfur
CIPAC No ‡	18
CAS No ‡	7704-34-9
EC No (EINECS or ELINCS) ‡	231-722-6
FAO Specification (including year of publication) ‡	/
Minimum purity of the active substance as manufactured ‡	990 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Open for the mined sulfur sources
Molecular formula ‡	S_8
Molecular mass ‡	32.064 (S)
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

<table>
<tr><td>Melting point (state purity) ‡</td><td>114 –120°C (>98 %)</td></tr>
<tr><td>Boiling point (state purity) ‡</td><td>444.6°C (secondary literature) (purity not given)</td></tr>
<tr><td>Temperature of decomposition (state purity)</td><td>Not relevant</td></tr>
<tr><td>Appearance (state purity) ‡</td><td>Yellow powder (99.9%)</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Vapour pressure (state temperature, state purity) ‡</td><td>$9.8 . 10^{-5}$ Pa (99.5 – 100.5%) at 20°C</td></tr>
<tr><td>Henry’s law constant ‡</td><td>0.05 Pa.m^{3}.mol^{-1} (20°C) (99.5 – 100.5%)</td></tr>
<tr><td>Solubility in water (state temperature, state purity and pH) ‡</td><td>63 ± 15 µg/L at 20°C (99.5 – 100.5%)</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Solubility in organic solvents ‡
(state temperature, state purity)</td><td>Purity, temperature not given
<table>
<tr><th>Solvent</th><th>Solubility (g/L)</th></tr>
<tr><td>n-hexane</td><td>1.8</td></tr>
<tr><td>Toluene</td><td>15.7</td></tr>
<tr><td>Dichloromethane</td><td>11.0</td></tr>
<tr><td>methanol</td><td>0.19</td></tr>
<tr><td>acetone</td><td>0.48</td></tr>
<tr><td>Ethyl acetate</td><td>1.03</td></tr>
</table></td></tr>
<tr><td>Surface tension ‡
(state concentration and temperature, state purity)</td><td>Not applicable</td></tr>
<tr><td>Partition co-efficient ‡
(state temperature, pH and purity)</td><td>Not applicable</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Dissociation constant (state purity) ‡</td><td>Not relevant</td></tr>
<tr><td>UV/VIS absorption (max.) incl. ε ‡
(state purity, pH)</td><td>Purity 99.9%

The molar extinction coefficients were determined to be:
<table>
<tr><td>Wavelength [nm]</td><td>molar extinction coefficient [L / mol · cm]</td></tr>
<tr><td>220
264
300</td><td>1451
805
400</td></tr>
</table></td></tr>
<tr><td>Flammability ‡ (state purity)</td><td>not highly flammable (99.9%)</td></tr>
<tr><td>Explosive properties ‡ (state purity)</td><td>no explosive properties (assessment)</td></tr>
<tr><td>Oxidising properties ‡ (state purity)</td><td>Sulfur has no oxidising properties (>98 %)</td></tr>
</table>

Summary of representative uses evaluated (*Sulfur*)

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Cereals-Barley, rye & wheat	Germany	KUMULUS WG	F	Erysiphe graminis	WG	Sulfur 80 % (w/w)	foliar spray	BBCH 25-77	1-2	14	1.2 - 3.2	200 - 400	4.8-6.4	35	[1] [2] [3]
Cereals-barley, rye & wheat	Germany	NETZSCH-WEFEL STULLN	F	Erysiphe graminis	WG	Sulfur 80% (w/w)	foliar spray	BBCH 25-77	1-2	14	1.2 - 3.2	200 - 400	4.8-6.4	35	[1] [2] [3]
Cereal Group	Germany	THIOVIT JET 80 WG	F	Erysiphe graminis	WG	Sulfur 80% (w/w)	foliar spray	BBCH 25-77	1-2	14	1.2 - 3.2	200 - 400	4.8-6.4	35	[1] [2] [3]
Cereal Group	France	MICROTHIOL DISPERSS	F	Oidium	WG	Sulfur 80% (w/w)	foliar spray	BBCH 25-77	1-2	14	1.2 - 3.2	200-600	4.8-6.4	35	[1] [2] [3]
Grapes	Germany	KUMULUS WG NETZSCH-WEFEL STULLN	F	Uncinula necator	WG	Sulfur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	0.16 - 0.64	400 - 1600	2.56	28	[1]

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Grapes	Germany	KUMULUS WG NETZSCH-WEFEL STULLN	F	Uncinula necator	WG	Sulfur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	0.5-2	400 - 1600	8	28	[1] [3] [4]
Grape Group	France	THIOVIT JET 80 WG	F	Uncinula necator	WG	Sulfur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	1.28-2.56	200-1000	2.56	28	[1]
Grape Group	France	THIOVIT JET 80 WG	F	Uncinula necator	WG	Sulfur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	0.8-4	200-1000	8	28	[1] [3] [4]
Grape Group	France	MICROTHIOL DISPERSS	F	Acarios and Erinose	WG	Sulfur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	0.256-1.28	200-1000	2.56	28	[1]
Grape Group	France	MICROTHIOL DISPERSS	F	Acarios and Erinose	WG	Sulfur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	0.8-4	200-1000	8	28	[1] [3] [4]

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Grapes	North & South EU	Sulphur 80 WG	F	Powdery mildew	WG	80 % (w/w)	spray	To beginning of ripening	5	7-10 days	2.700-4.000	200-300	2.56	28	[1]
Grapes	North & South EU	Sulphur Dust	F	Powdery mildew	DP	98.5 % (w/w)	dust	To beginning of ripening	5	7-10 days	Not applicable	Not applicable	19.7 - 29.55	5	[1] [3] [4]
Grapes	North & South EU	Sulphur 80 WG	F	Powdery mildew	WG	80 % (w/w)	spray	To beginning of ripening	5	7-10 days	2;700-4;000	200-300	8	28	[1] [3] [4]

[1] A data gap for a study with sediment dwelling organisms was identified and further refinement is needed for the risk assessment for sensitive non-target arthropods

[2] The risk assessment for herbivorous birds needs refinement (for applications at early growth stages)

[3] The risk assessment for insectivorous birds needs refinement (for application rates of 6.4 kg a.s./ha in cereals and for application rates of 8, 19.7 and 29.5 kg a.s./ha in grapes)

[4] The risk assessment for mammals needs refinement

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	**Sulfur Working Group** : HPLC/UV (not validated) : regression coefficient for linearity required **Sulfur Task Force** : HPLC/UV CIPAC method 18/TC/M/3 (iodometric method)
Impurities in technical as (analytical technique)	**Sulfur Working Group** : electrothermal atomic absorption spectrometry (ETAAS) and cold vapour atomic absorption spectrometry (CVAAS) (not validated). All impurities is < 0.1%. So, no other data required **Sulfur Task Force** : Optical Emission Spectroscopy Detector (ICP/OES) (not validated). All impurities is < 0.1%. So, no other data required.
Plant protection product (analytical technique)	**Sulfur Working Group** : CIPAC method 18/TC/M/3 (iodometric method) (validated for THIOVIT jet 80 WG and KUMULUS WG) HPLC/UV (validated for KUMULUS WG) Methods required for NETZCHWEFEL and MICROTHIOL DISPERSS **Sulfur Task Force** : CIPAC method 18/TC/M/3 (iodometric method) (validated for SULFUR 80 WG) HPLC/UV (validated for SULFUR DUST)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Not relevant
Food of animal origin		Not relevant
Soil		Not relevant
Water	surface	Not relevant
	drinking/ground	Not relevant
Air		Not relevant

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	No MRL, no method required. Nevertheless, one method using HPLC/UV (fully validated) was provided LOQ : 5 mg/kg for cereals LOQ : 10 mg/kg for grapes (not fully validated) Multi residue method (fully validated for grapes with LOQ 0.12 mg/kg and not validated for cereals) However, there was no ILV
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No MRL. No method required
Soil (analytical technique and LOQ)	No method required. Nevertheless, one method using HPLC/UV (not validated : no raw data provided and no confirmatory method) was provided
Water (analytical technique and LOQ)	No method required
Air (analytical technique and LOQ)	No method required
Body fluids and tissues (analytical technique and LOQ)	No method required

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	well absorbed at low dose levels based on human studies
Distribution ‡	Uniformly distributed.
Potential for accumulation ‡	No potential for accumulation.
Rate and extent of excretion ‡	No data. Not required. Homeostasis maintained.
Metabolism in animals ‡	Extensively metabolised to sulphates and sulphides.
Toxicologically relevant compounds ‡ (animals and plants)	Sulfur
Toxicologically relevant compounds ‡ (environment)	Sulfur

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.43 mg/L (4 h/nose only)	
Skin irritation ‡	Irritating	Xi R38
Eye irritation ‡	Not Irritating	
Skin sensitisation ‡	Non sensitising [M and K test]	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No effects	
Relevant oral NOAEL ‡	NOAEL > 1000 mg/kg bw/d (28-d rat) NOAEL > 1000 mg/kg bw/d (90-d rat)	
Relevant dermal NOAEL ‡	28-d rats: NOAEL 400 mg/kg bw/d Local reversible dermal hyperkeratosis at 1000 mg/kg bw/day	
Relevant inhalation NOAEL ‡	No data. Not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	No genotoxic potential	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	No data. Not required	
Relevant NOAEL ‡		
Carcinogenicity ‡		

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data. Not required	
Relevant parental NOAEL ‡		
Relevant reproductive NOAEL ‡		
Relevant offspring NOAEL ‡		

Developmental toxicity

Developmental target / critical effect ‡	No data. Not required	
Relevant maternal NOAEL ‡		
Relevant developmental NOAEL ‡		

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data. Not required	
Repeated neurotoxicity ‡		
Delayed neurotoxicity ‡		

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data. Not required
Studies performed on metabolites or impurities ‡	

Medical data ‡ (Annex IIA, point 5.9)

	No reports of adverse effects available from the manufacturers. Ocular disturbances, chronic sinusal effects, chronic bronchitis in sulfur mine workers. Skin & eye irritation in field and vine grape workers

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	None allocated		
AOEL ‡	Not necessary		
ARfD ‡	None allocated		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	Sulfur 80 WG products: 10 % (concentrate and most dilute, default value) Sulphur 98.5 DP: 10 % (default value)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Sulfur 80 WG products: Negligible compared to background levels Sulphur 98.5 DP: No data
Workers	Sulfur 80 WG products: Negligible compared to background levels Sulphur 98.5 DP: No data
Bystanders	Sulfur 80 WG products: Negligible compared to background levels Sulphur 98.5 DP: No data

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal: Xi R38
Substance classified (name)	Sulfur

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Cereals (Wheat, foliar application)
Rotational crops	Not applicable
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	No study on the nature of the residue was performed in processed commodities.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	None
Plant residue definition for risk assessment	None required as no ADI and ARfD was set
Conversion factor (monitoring to risk assessment)	Not applicable
Animals covered	Food producing animals (animal health and nutrition literature review) Sulfur is a natural product transformed into sulfate by all the animals.
Time needed to reach a plateau concentration in milk and eggs	Not applicable
Animal residue definition for monitoring	None
Animal residue definition for risk assessment	None required
Conversion factor (monitoring to risk assessment)	Not applicable as no ADI and ARfD was set
Metabolism in rat and ruminant similar (yes/no)	Not applicable
Fat soluble residue: (yes/no)	Not applicable

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Not required

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Elemental Sulfhur is stable.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3) **Note**: **not peer reviewed**

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 37 mg/kg DM/d for beef cattle	No	Not applicable
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not applicable	Not applicable	Not applicable
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg Not applicable		
Muscle	Not required	Not required	Not required
Liver	Not required	Not required	Not required
Kidney	Not required	Not required	Not required
Fat	Not required	Not required	Not required
Milk	Not required		
Eggs		Not required	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Cereals (barley and wheat)	N	<0.3; <0.5; 8x <1; 1	No extrapolation to southern Europe	Not applicable	1	0.89
Grapes (WP formulation)	N	0.01;; 0.25;; 0.33; 0.40; 0.54; 0.62; 1.87; 2.28; 5	No extrapolation to southern Europe	Not applicable	5	0.54
Grapes (DP formulation)	S	6; 9; 12; 20; 37; 68; 77; 154	No extrapolation to northern Europe	Not applicable	154	28

Note: for information only - not peer reviewed

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	None allocated
TMDI (% ADI) according to WHO European diet	Not required
TMDI (% ADI) according to national (to be specified) diets	Not required
IEDI (WHO European Diet) (% ADI)	Not required
NEDI (specify diet) (% ADI)	Not required
Factors included in IEDI and NEDI	Not applicable
ARfD	None allocated
IESTI (% ARfD)	Not required
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not required
Factors included in IESTI and NESTI	Not applicable

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Grapes/ wine making/wine	8	>380		

Note: for information only - not peer reviewed

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

.Grapes, cereals	**It is proposed not to set any MRL for Elemental sulfhur and that sulfur should be placed in Annex IV of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005.**

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)	
Mineralization after 100 days ‡	Not applicable to an active substance that is a mineral
Non-extractable residues after 100 days ‡	Not applicable to an active substance that is a mineral
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Not applicable to an active substance that is a mineral

Sulfur transformation in soil is governed by oxidation. Main transformation products are sulphates which are part of Sulfur cycle.

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	
Mineralization after 100 days	Not applicable to an active substance that is a mineral
Non-extractable residues after 100 days	Not applicable to an active substance that is a mineral
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable to an active substance that is a mineral
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable to an active substance that is a mineral

Rate of degradation in soil[9] (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X[10]	pH	t. °C	DT_{50} (d)	DT_{50} (d) 20 C pF2/10kPa	St. (r^2)	Method of calculation
							-
Geometric mean/median							

The available information only enables a qualitative assessment on the oxidation rates of elemental sulfur

Met 1	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 C pF2/10kPa	St. (r^2)	Method of calculation
No study submitted								
Geometric mean/median								

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
No valid study									
Geometric mean/median									

Met 1	Aerobic conditions								
Soil type	Location		pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r2)	DT_{50} (d) Norm.	Method of calculation
No study submitted									
Geometric mean/median									

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[9] transformation rate = time required for the oxidation of 50% of the applied elemental Sulfur

[10] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

pH dependence ‡ (yes / no) (if yes type of dependence)	
Soil accumulation and plateau concentration ‡	No study submitted

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[11]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 C pF2/10kPa	St. (r^2)	Method of calculation
No study submitted							
Geometric mean/median							

Met 1	Anaerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 C pF2/10kPa	St. (r^2)	Method of calculation
No study submitted								
Geometric mean/median								

Soil adsorption/desorption (Annex IIA, point 7.1.2)							
Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	K_{foc} (mL/g)	1/n
No valid study							
Arithmetic mean/median							
pH dependence, Yes or No							
Calculation of K_{oc} from Sw (water solubility = 63 µg/L)				1950			

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[11] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Metabolite 1 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
No study submitted							
Arithmetic mean/median							
pH dependence (yes or no)							

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)	
Column leaching ‡	No valid study
	-
Aged residues leaching ‡	No study submitted
	-
	-*
Lysimeter/ field leaching studies ‡	Location: England Study type (e.g.lysimeter, field): lysimeter Soil properties: texture, pH = 6.6, OC = 12.7 g/kg Dates of application : Sept 1996 to Sept 1999 Crop : /Interception estimated: Number of applications: 1 application the first year Duration. 3 years Application rate: 50 kg/ha/year + 22 kg atmospheric deposition Average annual rainfall (mm): 615.3 Average annual leachate volume (mm): 214 Leaching rate of organic forms over the three years: equivalent to 68 kg/ha of Sulfur as SO_4^{2-} + 4.8 kg/ha as DOS (dissolved organic Sulfur) = 72.8 kg/ha, when 72 kg/ha input. No elemental Sulfur leached.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): -

Application data	Crop: Wheat Sulfur form: 80%WG Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 50% Number of applications: 2 Interval (d): 14 Application rate(s): 6400 g as/ha Annual application rate: 12800 g as/ha/y

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Maximum PEC			8.5	

Parent Method of calculation	DT$_{50}$ (d): -
Application data	Crop: Barley Sulfur form: 80%WG Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 50% Number of applications: 2 Interval (d): 14 Application rate(s): 4800 g as/ha Annual application rate: 9600 g as/ha/y

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Maximum PEC			6.4	

Parent Method of calculation	DT$_{50}$ (d): -

Application data	Crop: Grapes Sulfur form: 80%WG Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 70% Number of applications: 8 Interval (d): 7 Application rate(s): 8000 g as/ha Annual application rate: 64000 g as/ha/y

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Maximum PEC			25.6	

Parent Method of calculation	DT$_{50}$ (d): -
Application data	Crop: Grapes Depth of soil layer: 5cm Sulfur form: Dust Soil bulk density: 1.5g/cm^3 % plant interception: 70% (average for all the applications) Number of applications: 5 Interval (d): 5 Application rate(s): 29550 g as/ha Total annual application rate: 44325 g as/ha/y

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Maximum PEC			59.1	

Metabolite I Method of calculation	-
Application data	-

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Not determined				

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Not relevant, water solubility: 63 µg/L
Photolytic degradation of active substance and metabolites above 10 % ‡	Direct photolysis (study conducted in organic solvent on a glass plate – can not be extrapolated to water)
Quantum yield of direct phototransformation in water at > 290 nm	-
Readily biodegradable ‡ (yes/no)	Not relevant, inorganic substance

Degradation in water / sediment

Parent	Distribution (eg max in water *x* after *n* d. Max. sed x % after *n* d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
No study submitted, not required										
Geometric mean/median										

Metabolite 1	Distribution (eg max in water *x* after *n* d. Max. sed x % after *n* d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
No study submitted, not required										
Geometric mean/median										

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
No study submitted, not required					

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

A data gap was identified by EFSA after the experts’ meeting for PECsed calculations.

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Calculated for sulphates with worst case hypothesis: - 100% of Sulfur is oxidised to sulphate - 100% of sulphate leaches - water volume leached in 26 years
Application rate	Application rate: 30000 g/ha. No. of applications: 5/years Calculations for 26 years Crop: grapes Time of application (month or season): autumn Crop interception: 85%

PEC(gw) - Calculated results (based on total water volume percolated at 1m, during 26 years)

Model /Crop	Scenario	Sulphate (mg/L)	Metabolite (µg/L)		
			1	2	3
	Chateaudun	17.7			
	Hamburg	25.8			
	Jokioinen	-			
	Kremsmunster	21.5			
	Okehampton	-			
	Piacenza	14.6			
	Porto	15.9			
	Sevilla	81.4			
	Thiva	28.4			

PEC$_{(gw)}$ From lysimeter / field studies

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	-	-	-

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)	-	-	-

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air ‡	-
Volatilisation ‡	Not volatile
Metabolites	None

PEC (air)

Method of calculation	Not applicable - Vapour pressure = $9.8.10^{-5}$ Pa at 20°C

PEC$_{(a)}$

Maximum concentration	e.g. negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Sulfur Surface Water: Sulfur Sediment: Sulfur Ground water: Sulfur and sulphates Air: Sulfur

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Biodegradability assessment not applicable for a mineral

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
C. coturnix japonica	**Sulfur Dust**	**Acute**	**> 2000[a] mg a.s./kg bw**	
C. coturnix japonica	**Sulfur 80WG**	**Acute**	**> 2000[a] mg PP/kg bw**	
C. virginianus	Sulfur	Short-term	**> 1334.75 mg a.s./kg bw/day**	> 5339 mg a.s./kg
Mammals ‡				
Rat	Sulfur	Acute	> 1760 mg/kg bw	
	Sulfur	**Acute**	**> 5000[a] mg/kw bw**	
	Sulfur dust	Acute	> 2000 mg/kg bw	
	Sulfur	Short-term	> 1000 mg/kg bw (NOEL)	
	Sulfur	Short-term	> 1000 mg/kg bw (NOEL)	
Rat		Long term	no submitted studies	
Additional higher tier studies ‡				
None				

a: endpoint used for the risk assessment

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Cereals (4.8 and 6.4 kg a.s./ha)

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Insectivorous/ late stage	Acute	259.58	> 7.70	10
	Acute	346.11	> 5.78	10
	Short-term	144.77	> 9.22	10
	Short-term	193.02	> 6.91	10

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Herbivorous / early stage	Acute	360	> 5.56	10
	Acute	480	>4.17	10
	Short-term	221	> 9.04	10
	Short-term	295	> 6.8	10
Higher tier refinement (Birds)				
Insectivorous/ late stage (Cereals 4.8 kg as/ha)	Acute	217[4]	> 9.21	10
	Acute	58.5[5]	> 34.2[6]	10
Insectivorous/ late stage (Cereals 6.8 kg as/ha)	Acute	289[4]	> 6.91	10
	Acute	89.6[5]	> 22.3[6]	10
Insectivorous/ late stage (Cereals 4.8 kg as/ha)	Short-term	121[4]	> 11	10
	Short-term	21[5]	> 63	10
Insectivorous/ late stage (Cereals 6.8 kg as/ha)	Short-term	161[4]	> 8.3	10
	Short-term	21.7[5]	> 47	10
Tier 1 (Mammals)				
Insectivorous/ late stage	Acute	42.34	> 118.10	10
	Acute	56.45	> 88.58	10
Higher tier refinement (Mammals)				
None				

[1] higher tier refinement of the risk assessment on insectivorous birds in cereals was based on the yellow wagtail (*Motacilla flava*) as focal species. Two ways of exposure were considered for the acute and short-term risk to yellow wagtail: based only on small insects or only on large insects.

[2] for cereals indicate if it is early or late crop stage

[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

[4] based on a diet of small insects

[5] based on a diet of large insects

[6] TER values were corrected by EFSA after peer review, using a corrected ETE based on a RUD value of 14 for large insects (instead of the RUD for small insects, which was applied in the final corrigendum (Vol. 3, B.9, Corrigendum, November 2008))

Grapes (2.56, 8, 19.7 and 29.5 kg a.s./ha)

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Insectivorous	Acute	302.46	> 11.2	10
	Acute	432.64	> 4.62	10
	Acute	1065.38	> 1.88	10
	Acute	1595.36	> 1.25	10
	Short-term	77.2	> 17.3	10

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
	Short-term	241.28	> 5.53	10
	Short-term	594.15	> 2.25	10
	Short-term	891.23	> 1.50	10
Higher tier refinement (Birds)				
Not accepted during the PRAPer Meeting. Still needs to be addressed				
Tier 1 (Mammals)				
Herbivorous				
2.56 kg S/ha	Acute	302.46	> 16.53	10
8 kg S/ha	Acute	945.2	> 5.29	10
19.5 kg S/ha	Acute	2327.56	> 2.15	10
29.5 kg S/ha	Acute	3491.3	>1.43	10
Higher tier refinement (Mammals)				
None				

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Secondary poisoning due to drinking water

Applicable only to WG form of Sulfur. Worst case assessment.

Application rate	Application rate: 8000 g/ha. Application volume: 200 L/ha Crop: grapes

$PEC_{drinking\ water}$ (mg/L)	Water ingestion rate (L)	Daily dose of active substance (mg/d/kg bw)	Toxicity (mg/L)	TER_a	Trigger value
Birds					
8[1]	0.0027	2.16	2000	925.9	10
Mammals					
8[1]	0.0036	1.45	5000	4348	10

[1]: as a suspension of granules

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg a.s./L)
Laboratory tests ‡				
Fish				
O. mykiss.	**Sulfur 80% WG**	**96 hr (static)**	**Mortality, EC_{50}**	**> 0.063[a] (sol lim)**
O. mykiss.	Sulfur Dust	96 hr (static)	Mortality, EC_{50}	> 0.063 (sol lim)
C. carpio	Sulfur 80% WG	96 hr (static)	Mortality, EC_{50}	> 0.063 (sol lim)
C. carpio	Sulfur 80% WG	96 hr (static)	Mortality, EC_{50}	> 0.063 (sol lim)
O. mykiss.	**Sulfur 80% WG**	**28 d(flow-through)**	**Growth NOEC**	**> 0.063[a] (sol lim)**
Aquatic invertebrate				
D. magna.	**Sulfur 80% WG**	**48 h (static)**	**Mortality, EC_{50}**	**> 0.063[a] (sol lim)**
D. magna.	Sulfur 80% WG	48 h (static)	Mortality, EC_{50}	> 0.063 (sol lim)
D. magna.	Sulfur Dust	48 h (static)	Mortality, EC_{50}	> 0.063 (sol lim)
Sediment dwelling organisms				
No study				
Algae				
S subspicatus.	Sulfur 80% WG	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 0.063 (sol lim)
S subspicatus.	**Sulfur Dust**	**72 h (static)**	**Biomass: E_bC_{50}** **Growth rate: E_rC_{50}**	**0.002[a] (mm)** **0.002[a] (mm)**
Higher plant				
No study				
Microcosm or mesocosm tests				
Not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s. - sol lim = solubility limit

a: endpoint used for the risk assessment

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Not applicable

Bioconcentration				
Not relevant				

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
Sulfur Dust	> 106.8	> 100
Sulfur 80% WG	> 100	> 100
Field or semi-field tests		
Not required		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Cereals 4.8 and 6.4 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
Sulfur 80% WG	Contact	< 48	50
Sulfur 80% WG	oral	< 48	50
Sulfur 80% WG	Contact	< 64	50
Sulfur 80% WG	oral	< 64	50

Grapes, 2.56, 8, 19.7 and 29.55 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
Sulfur 80% WG	Contact	< 25.6	50
Sulfur 80% WG	oral	< 25.6	50
Sulfur 80% WG	Contact	< 80	50
Sulfur 80% WG	oral	< 80	50
Sulfur Dust	Contact	< 197	50
Sulfur Dust	oral	< 184.5	50
Sulfur Dust	Contact	< 295.5	50
Sulfur Dust	oral	< 276.7	50

Hazard quotients for honey bees off-field

Grapes, 8, 19.7 and 29.55 kg a.s./ha – 8.02% drift at 3 m

Test substance	Route	Hazard quotient	Annex VI Trigger
Sulfur 80% WG	Contact	< 6.42	50
Sulfur 80% WG	oral	< 6.42	50
Sulfur Dust	Contact	< 15.8	50
Sulfur Dust	oral	< 14.8	50
Sulfur Dust	Contact	< 23.7	50
Sulfur Dust	oral	< 22.2	50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	Sulfur Dust	Mortality	10340
Aphidius rhopalosiphi ‡	Sulfur Dust	Mortality	486

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Cereals, 4.8 and 6.4 kg a.s./ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Sulfur	*Typhlodromus pyri*	10340	1.39	0.04 (1 m)	2
Sulfur	*Typhlodromus pyri*	10340	1.86	0.05 (1 m)	2
Sulfur	*Aphidius rhopalosiphi*	486	29.6	0.82 (1 m)	2
Sulfur	*Aphidius rhopalosiphi*	486	39.5	1.09 (1 m)	2

[1] indicate distance assumed to calculate the drift rate

Grapes, 2.56, 8, 19.7 and 29.5 kg a.s./ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Sulfur	*Typhlodromus pyri*	10340	0.74	0.06 (3 m)	2
Sulfur	*Typhlodromus pyri*	10340	2.32	0.19 (3 m)	2
Sulfur	*Typhlodromus pyri*	10340	5.72	0.46 (3 m)	2
Sulfur	*Typhlodromus pyri*	10340	8.6	0.7 (3 m)	2
Sulfur	*Aphidius rhopalosiphi*	486	15.8	1.27 (3 m)	2
Sulfur	*Aphidius rhopalosiphi*	486	49.5	4.0 (3 m)	2
Sulfur	*Aphidius rhopalosiphi*	486	121.6	9.8 (3 m)	2
Sulfur	*Aphidius rhopalosiphi*	486	182.1	14.6 (3 m)	2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)[1,2]	End point	% effect[3]	Trigger value
Aphidius rhopalosiphi	Adults	Sulfur 80% WG 48h	10000	Mortality	100	-
Aphidius rhopalosiphi	Adults	Sulfur 80% WG 48h	12720 16000 20160 25400 32000	Mortality	0.0 44.83 48.28 55.18 51.72 LR50 = 19.89	50 %
Aphidius rhopalosiphi	Adults	Sulfur 80% WG 48h	12720 16000 20160 25400 32000	Reproduction	3.06 + 27.61 12.6- - -	50 %
Aphidius rhopalosiphi	-	Sulfur 80% WG 48h	8000 16000 24000 32000 40000	Mortality	22.0 25.4 45.8 93.2 79.7 LR50 = 19600	50 %
Aphidius rhopalosiphi	-	Sulfur 80% WG 48h	8000 16000 24000 32000 40000	Parasitisation efficiency (% inhibition)	25.8 21.1 45.38 - -	50 %
T. cacoeciae	Adults	Sulfur 80% WG	812	Reproduction	100	50 %
T. cacoeciae	Adults	Sulfur 80% WG 48h	0.8 3.12 12.58 50 200 800	Reproduction	33.98 8.68 42.45 35.94 77.66 90.24 ER50 = 74	50 %
P. cupreus	Adults	Sulfur 80% WG 14 d	10000	Mortality Food consumption	0 4.2	50 %
C. carnea	Larvae	Sulfur 80% WG 21 d	10000	Mortality Fecundity	6 0	50 %
A. bilineata	Adults	Sulfur 80% WG 7 d	10000	Mortality Reproduction	0 2.3	50 %

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)[1,2]	End point	% effect[3]	Trigger value
T. pyri	Adults	Sulfur Dust 48h	5000 10000 20000 40000 60000	Mortality	21.8 12.8 20.1 63.7 25.5 LR50 > 60000	50 %
T. pyri	Adults	Sulfur Dust 48h	5000 10000 20000 40000 60000	Reproduction	50 51.4 44.4 - 84.7 NOEC < 5000	50 %
P. cupreus	Adults	Sulfur Dust 14 d	30000 90000	Mortality	0 0	50 %
P. cupreus	Adults	Sulfur Dust 14 d	30000 90000	Food consumption	1 3	50 %
C. carnea	Larvae	Sulfur Dust 21 d	30000	Mortality	60.4	50 %
C. carnea	Larvae	Sulfur Dust 48h	1250 2500 5000 10000 20000	Mortality	42.9 50.1 71.4 66.7 78.6 LR50 = 2000	50 %
C. carnea	Larvae	Sulfur Dust 48h	1250 2500 5000 10000 20000	Reproduction	9.45 0 - - -	50 %

[1] indicate whether initial or aged residues

[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

[3] positive percentages relate to no adverse effects (e.g. increasing of reproduction rate compared to the control)

Field or semi-field tests
Studies on grapes on 9 experimental sites selected in Germany. 8 applications per season for 1 experimental site, and 6 applications per season for the 8 other experimental sites Rate up to 2.56 kg a.s./ha Maximum short-term effects = 40% No impact on *T. pyri* populations after the 4-month duration study
Study in vineyard in Germany. *Typhlodromus pyri* – Predatory mites (Acari: Phytoseiidae) 5 applications: 30 kg product/ha ; 30 kg product/ha ; 25 kg product/ha ; 20 kg product/ha 20 kg product/ha NOEC ≥ field application rate (52% effect after 5 days since the last application; 46% effect after 30 days since the last application; the test was prolonged to 56 days after the last application, when the effect was 9.6%).
Study in vineyard in Italy. *Phytoseius plumifer* - Predatory mites (Acari: Phytoseiidae) 5 applications: 30 kg product/ha ; 30 kg product/ha ; 25 kg product/ha ; 20 kg product/ha 20 kg product/ha NOEC ≥ field application rate (Highest effect was 30% 6 days after the first application; -72% effect 31 days after the last application)

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
E. fetida	Sulfur 80% WG	Acute 14 days	LC50> 2000 mg product/kg LC50> 1576 mg a.s./kg
E. fetida	Sulfur 80% WG	Acute 14 days	LC50> 1000 mg product/kg LC50> 788 mg a.s./kg
E. fetida	Sulfur Dust	Acute 14 days	LC50> 1000 mg product/kg LC50> 985 mg a.s./kg

Test organism	Test substance	Time scale	End point[1]
Soil micro-organisms			
Nitrogen mineralisation	Sulfur Dust		0% effect at day 28 at 400 mg prod/kg d.w.soil (300 kg prod/ha)
	Sulfur 80% WG		at 13.3 mg prod./kg d.w.soil (10 kg prod/ha): - no effect during 77 days at 133 mg prod/kg d.w.soil (100 kg prod/ha): - 14% effect at day 77 - maximum effect of 86 % inhibition at day 21
Carbon mineralisation	Sulfur Dust		6% effect at day 28 at 40 mg prod/kg d.w.soil (30 kg prod/ha) 2% effect at day 28 at 400 mg prod/kg d.w.soil (300 kg prod/ha)
	Sulfur 80% WG		at 13.3 mg prod./kg d.w.soil (10 kg prod/ha): - no effect during 28 days at 133 mg prod/kg d.w.soil (100 kg prod/ha) - 6.3% effect (inhibition) at day 28 in sandy loam soil - 26.8% effect (inhibition) at day 28 in loamy sand soil
Field studies[2]			
Not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})

[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Cereals, 4.8 and 6.4 kg a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
E. fetida	Sulfur 80% WG	Acute	6.4 (max)	123	10
E. fetida	Sulfur 80% WG	Acute	8.5 (max)	92.7	10

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

Grapes, 8 and 29.5 kg a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
E. fetida	Sulfur 80% WG	Acute	25.6 (max)	30.8	10
E. fetida	Sulfur Dust	Acute	59.1[3] (max)	16.7	10

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)
[3] Max PEC_{soil} for the Sulfur Dust application was corrected by EFSA after the peer review.

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests
Cereals, application rate of 4800 and 6400 g a.s./ha

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure (2.77% drift at 1 m) (g a.s./ha)[2]	TER	Trigger
Zea mays *Avena sativa* *Allium cepa* *Brassica oleracea* *Pisum sativum* *Daucus carota*	Sulfur 80% WG	> 25200	-	133 177.3	> 189.5 > 142.1	5

Grapes, application rate at 8000, 19700 and 29550 g a.s./ha

Most sensitive species	Test substance	ER_{50} (g/ha)^2 vegetative vigour	ER_{50} (g/ha)^2 emergence	Exposure (8.02% drift at 1 m) (g a.s./ha)^2	TER	Trigger
Zea mays *Avena sativa* *Allium cepa* *Brassica oleracea* *Pisum sativum* *Daucus carota*	Sulfur 80% WG	> 25200	-	641.6 1580 2370	> 39.3 > 15.9 > 10.6	5

Additional studies (e.g. semi-field or field studies)

None

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	Not tested
Activated sludge	Not tested
Pseudomonas sp	Not tested

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	-
water	-
sediment	-
groundwater	-

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	NC

	RMS/peer review proposal
Preparation	NC

APPENDIX B – LIST OF ABBREVIATIONS

ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
CVAAS	cold vapour atomic absorption spectrometry
d	day
DAR	draft assessment report
DAA	days after application
DAT	days after treatment
DM	dry matter
DP	dustable powder
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EbC_{50}	effective concentration (biomass)
ErC_{50}	effective concentration (growth rate)
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EMEA	European Medicines Agency
ER_{50}	emergence rate/effective rate, median
ERR	extractable radioactivity
ETAAS	electrothermal atomic absorption spectrometry
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FIR	food intake rate
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
f(twa)	time weighted average factor
g	gram
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)

ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HQ	hazard quotient
ICP/OES	inductively coupled plasma/optical emission spectroscopy detector
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
ILV	inter laboratory validation
JMAF	Japanese Ministry of Agriculture, Farming and Fisheries
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
kg	kilogram
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC_{50}	lethal concentration, median
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
MAF	multiple application factor
µm	micrometer (micron)
µg	microgram
mg	milligram
mL	millilitre
M/L	mixing and loading
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{soil}	predicted environmental concentration in soil
$PEC_{sed.}$	predicted environmental concentration in sediment
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant

P_{ow}	partition coefficient between n-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
r^2	coefficient of determination
RMS	rapporteur member state
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first order
SSD	species sensitivity distribution
STMR	supervised trials median residue
TC	transfer coefficient
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TWA	time weighted average
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
W/S	water/sediment
yr	year

APPENDIX C – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
N/A		