

CONCLUSION ON PESTICIDE PEER REVIEW

Peer review of the pesticide risk assessment of the active substance sulfur¹

Question No EFSA-Q-2008-393

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SUMMARY

Sulfur is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004², as amended by Regulation (EC) No 1095/2007³. 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.

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 PEC_{sw} 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 PEC_{sed} 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