

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance sulfuryl fluoride¹

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SUMMARY

Sulfuryl fluoride is a new active substance for which, in accordance with Article 6(2) of Council Directive 91/414/EEC³, the United Kingdom received an application from Dow AgroSciences for inclusion in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision 2003/305/EC⁴.

Following the agreement between the Commission of the European Communities (hereafter referred to as 'the Commission') and the EFSA for the EFSA to organise a peer review of those new active substances for which the decision on the completeness of the dossier had been published after June 2002, the designated rapporteur Member State (RMS), the United Kingdom, made the report of its initial evaluation of the dossier on sulfuryl fluoride, hereafter referred to as the Draft Assessment Report (DAR), available on 29 October 2004.

The peer review was initiated on 9 November 2004 by dispatching the DAR for consultation of the Member States and the applicant. Subsequently, the comments received on the DAR were examined by the RMS and the need for additional data was agreed in an evaluation meeting on 28 September 2005. Remaining issues as well as further data made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in September 2006.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 27 September 2007, leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as an insecticide, comprising application as a fumigant in food storage to control all life stages of arthropods (e.g. meal moth, flour and grain beetles) in emptied flour mills and empty grain storage facilities at maximum concentrations of 128 g/m³ (CTP =1500 (Concentration X Time Product)). Details of the applications and timings can be found in the list of end points. The uses submitted in the DAR on dried fruit and tree nut commodities were withdrawn by the applicant for the EU evaluation.

¹ On request from the European Commission, Question No EFSA-Q-2009-00311, issued on 17 December 2009.

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³ OJ No L 230, 19.8.1991, p. 1. Directive as last amended by L 20, 22.1.2005, p.19

⁴ OJ No L 112, 6.5.2003, p.10

The representative formulated product for the evaluation was 'ProFume', a gas (GA), registered under different trade names in Europe. The formulation contains 99.4% w/w sulfuryl fluoride pure (the technical active substance is the product).

Analytical methodology is available for the determination of the active substance and the impurities in the technical material as manufactured and for the active substance in the formulation, which is in practice the technical material.

Several methods are available to monitor the compounds given in the respective residue definitions for food of plant origin, in blood and urine, however additional data may be required after the finalization of the residue definitions in the different matrices. A data gap was identified for a method for residues in air.

With regard to mammalian toxicity, sulfuryl fluoride has been classified (29th ATP, Commission Directive 2005/73/EC⁵) as T; R23 'Toxic by inhalation' based on reported deaths in humans. In addition, the experts' meeting proposed classification as T; R25 'Toxic if swallowed' and Xi; R37 'Irritating to the respiratory system'. It was also classified as Harmful; R48/20 'Danger of serious damage to health by prolonged exposure/inhalation route'. The relevant short-term exposure No Observed Adverse Effect Levels (NOAELs) are 30 ppm in mice and rabbits, 20 ppm in dogs and 100 ppm in rats based on slight renal hyperplasia and mineralisation at 300 ppm. In rats and mice the long-term NOAEL is 20 ppm. Sulfuryl fluoride does not show any genotoxic or carcinogenic potential. It is not a reproductive or developmental toxicant. In multigeneration studies the parental NOAEL was 5 ppm while the NOAEL in offspring was 20 ppm based on reduced growth during lactation at 150 ppm. The lowest relevant developmental NOAEL is 75 ppm, from the rabbit study. The NOAEL for the acute study in rats is 300 ppm. The Acceptable Daily Intake (ADI) is 0.014 mg/kg bw/day, based on the long term toxicity study in rats, with a safety factor of 100. The Acute Reference Dose (ARfD) is 0.7 mg/kg bw and the Acceptable Operator Exposure Concentration (AOEC) resulted in 1 ppm. For the bystander exposure assessment, an AOEC of 3 ppm was set. The RMS proposed that operators introducing fumigant or carrying out tasks associated with the aeration procedure should wear suitable respiratory protective equipment. Based on the available data, a 10 metre exclusion zone around the fumigated structure was considered to protect unprotected persons (i.e. bystanders) from levels of sulfuryl fluoride above 3 ppm.

Metabolism studies that address the nature of the residues on food commodities upon fumigation with sulfuryl fluoride were not submitted. Therefore it was discussed by experts whether the metabolism or mode of degradation, respectively, of sulfuryl fluoride in food and feed commodities was sufficiently addressed and whether there was satisfactory proof from the information and papers submitted, that the proposed breakdown mechanism is identical in all matrices as suggested by the applicant. The experts concluded that the available information is not sufficient to assess the involved reactions, to verify the reported results and to confirm that sulfuryl fluoride and free fluoride ion will be the only relevant residues the consumer may be exposed to. Therefore the consumer risk assessment, mainly with regard to the nature of the residue, cannot be finalised.

Even though uses on the fumigation of food items (dried fruits, nuts) were withdrawn during the peer review procedure and only uses for structural treatments remain, there is still the potential for consumer exposure to inorganic fluoride through contaminated products, such as flour and bran that remained in the mill machinery during fumigation, or grain stored in silos in the mill. Available data show that high fluoride residue levels in flour and bran occurred after the production in a treated mill structure had been taken up again. Therefore measures to avoid contaminated cereal products getting into the food chain are necessary if, in practice, contamination cannot be avoided.

The RMS suggested separate MRLs for fluoride ion should be proposed based on background levels. However, there are currently no agreed acceptable fluoride background levels in food products in the

⁵ OJ L 216, 16.6.2004

EU and therefore the allocation of an adequate MRL for fluoride might be difficult. Any higher MRL than at natural background levels would trigger a consumer exposure and risk assessment. It is noted that such assessment will also need to consider other sources of fluoride exposure.

Sulfuryl fluoride is a gas under all environmental conditions (boiling point -54°C). The vapour pressure is deemed to be high according to the available data. Potential degradation routes for sulfuryl fluoride were analysed in the DAR. All routes were considered negligible except the chemical hydrolysis that may occur in ocean waters.

The initial assessment of the fate and behaviour of sulfuryl fluoride in the environment was based on a limited set of experimental data (essentially limited to the physical and chemical properties of the substance) and a number of assumptions and indirect information (such as production figures and atmospheric half-life) that were used as input parameters in the fugacity models employed for the assessment of the fate and behaviour of the substance at global scale. Assessment of the fate and behaviour of sulfuryl fluoride at the field scale level was not presented by the applicant in the initial submission. Also the fate and behaviour of hydrolysis transformation products was not addressed. A number of data gaps were identified in the early stages of the peer review to properly document the information used in the assessment.

One of the key parameters used in the assessment is the atmospheric lifetime. The value used by the applicant was derived from a presumed monitored tropospheric concentration only available by a personal communication of one of the scientists involved. The experts' meeting considered that the data provided were not sufficiently documented for regulatory purposes and identified a data gap for the determination of atmospheric lifetime.

At the experts' meetings (PRAPeR 02 and 03) on environmental fate and behaviour and ecotoxicology, respectively, the RMS was asked to undertake further assessments: in particular on wet deposition and the potential for contamination of soil and water by metabolites of sulfuryl fluoride; to evaluate field-scale PEC values in soil and surface water close to treated installations and revised fugacity modelling to calculate global-scale PECs in soil, water and air. Additional estimates were also requested for global warming potential (GWP), based on worst case atmospheric lifetime and anticipated sales volumes. These points have been largely addressed by the RMS in addendum 3 of May 2007 based on the information provided by the applicant. However, the assessment provided by the applicant and presented by the RMS in the addendum did not strictly follow the scenario approach proposed by the experts' meeting (only lifetime of 4.5 yr was used and production figures were generally limited to historical records from 1992-2000) and did not take into consideration most recent information available at the time on the occurrence of sulfuryl fluoride in the atmosphere. This information is crucial since it supersedes the information used by the applicant to estimate the atmospheric lifetime of the substance on which most of the fate and behaviour assessment of sulfuryl fluoride is based. As a consequence, EFSA had redone parts of the modelling presented by the applicant and the RMS in addendum 3 of May 2007. The most relevant results are presented in the EFSA conclusion, and the background input parameters and calculations are documented in the EFSA addendum of July 2007.

With respect to the field scale assessment, EFSA did a preliminary sensitivity analysis of the assumptions used in the field scale soil assessment (based on LEVEL I fugacity model) and added some considerations to address the transformation products of sulfuryl fluoride at field scale. Neither the RMS addendum 3 nor the EFSA addendum has been peer reviewed.

A number of data gaps were identified during the peer review. The main areas of concern from the fate and behaviour point of view are the high uncertainty associated with the atmospheric lifetime (best available estimate was about 15 yr) and the intrinsic global warming potential that needed to be re-calculated. At the time of finalising this conclusion values previously estimated based on measurements of the AGAGE (Advanced Global Atmospheric Gases Experiment) network have been refined and a longer atmospheric lifetime than previously reported is recently quoted in the scientific

literature (36 ± 11 yr). Based on these recent data, a GWP of 4780 for the 100 years horizon has been published.

Sulfuryl fluoride is very toxic to aquatic organisms. However, due to the specific use and the physical-chemical properties of the substance, exposure of non-target organisms is considered negligible and hence the risk to non-target organisms is considered to be low.

KEY WORDS

sulfuryl fluoride, peer review, risk assessment, pesticide, insecticide

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BACKGROUND

Legislative framework

In accordance with Article 6(2) of Council Directive 91/414/EEC⁶ the United Kingdom received an application from Dow AgroSciences for inclusion of the active substance sulfuryl fluoride in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision 2003/305/EC⁷.

Following the agreement between the Commission of the European Communities (hereafter referred to as 'the Commission') and the EFSA for the EFSA to organise a peer review of those new active substances for which the completeness of the dossier had been officially confirmed after June 2002, the designated rapporteur Member State (RMS), the United Kingdom, submitted the report of its initial evaluation of the dossier on sulfuryl fluoride, hereafter referred to as the Draft Assessment Report (DAR) (UK, 2004), to the EFSA on 29 October 2004. The DAR was distributed for consultation to the Member States and the applicant on 9 November 2004.

The comments received on the DAR were evaluated and addressed by the RMS. Based on this evaluation, representatives from the Member States identified and agreed in an evaluation meeting on 28 September 2005 on data requirements to be addressed by the applicant, as well as issues for further detailed discussion at expert level. A representative of the applicant also attended this meeting.

Taking into account the information received from the applicant addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in experts' meetings organised in Parma in September 2006. 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 with representatives from Member States on 27 September 2007, leading to the conclusions as laid down in this report.

Following the agreement between the Commission and the EFSA regarding the peer review of new active substances, 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. A list of the relevant end points 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 (EFSA, 2009) comprising the documents summarising and addressing the comments received on the initial evaluation provided in the DAR:

- the comments received
- the resulting reporting table (rev. 1-2, 25 May 2006)

as well as the documents summarising the follow-up of the issues identified as not finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1, 27 September 2007)

⁶ OJ L 230, 19.8.1991, p.1. Directive as last amended by L 20, 22.1.2005, p.19

⁷ OJ L 112, 6.5.2003, p.10

Given the importance of the DAR including its addendum (compiled version of January 2009 containing all individually submitted addenda) (UK, 2009) 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

There is no ISO common name for sulfuryl fluoride, it has been used in the literature but has no official status except as a systematic name. The IUPAC name is sulfuryl fluoride.

Sulfuryl fluoride is a non-specific insecticide that acts by disrupting the glycolysis and citric acid cycles, depriving the organism of the necessary energy for survival. Sulfuryl fluoride is used for the control of all life stages of arthropods (e.g. meal moths, flour and grain beetles) in emptied flour mills and empty grain storage facilities.

The representative formulated product for the evaluation was 'ProFume', a gas (GA), registered under different trade names in Europe. The formulation contains 99.4% w/w sulfuryl fluoride pure (the technical active substance is the product).

The initial evaluated representative uses as a post-harvest insecticide comprise fumigation of buildings or storage containers by releasing gas from a cylinder, to control stored product insect pests (eg. *Ephestia kuehniella*, *Plodia interpunctella*, *Tribolium castaneum*, *Tribolium confusum*, *Trogoderma variable*, *Oryzaephilus surinamensis*) in emptied cereal grain mills, and post-harvest use, to control stored product insect pests (eg *Oryzaephilus surinamensis*, *Trogoderma variable*), as well as Lepidoptera pests (such as *Ephestia kuehniella*, *Plodia interpunctella*) in dried fruits and tree nuts, with dosages determined by insect species, life stage and temperatures, with the maximum target dosage of 1500 CTP g h/m³ with a maximum target concentration of 128 g/m³. However it should be noted that the uses submitted in the DAR on dried fruit and tree nut commodities were withdrawn by the applicant for the EU evaluation.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of sulfuryl fluoride is 99.4%. No FAO specification exists.

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 sulfuryl fluoride or the respective formulation. The vapour pressure was calculated using data from a non-GLP study with the Antoine equation, which is not part of the EEC method A4. The experts at PRAPeR Meeting 01 (September 2006) were unable to confirm the vapour pressure value calculated and requested additional information. The submitted study was accepted by the EFSA, however, it was not peer reviewed and a data gap was maintained for formal reasons.

Adequate analytical methods are available for the determination of sulfuryl fluoride in the technical active substance and in the plant protection product by GC-TCD. Satisfactory methods were submitted for the determination of impurities in the technical active substance.

Several analytical methods for the determination of sulfuryl fluoride residues in a number of different commodities are available, using headspace analysis with GC-ECD, or extraction with de-ionised water and detection with fluoride ion-specific electrode, however additional data may be required after the finalization of the residue definitions in the different matrices.

For soil and water no enforcement methods are needed due to the fact that sulfuryl fluoride concentrations estimated to occur as a consequence of the proposed uses are some orders of magnitude below the measurable amounts with the available analytical technology.

An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

Adequate published analytical methods for the determination of sulfuryl fluoride residues (fluoride ion) in blood and urine are available. However it should be noted that since the fluoride ion is also available from other sources, and that natural occurrence in the body is evident, this might not be the appropriate target analyte, since it is not specific to sulfuryl fluoride.

An analytical method for the determination of sulfuryl fluoride residues in air with the limit of determination 0.4 mg/m³ is available, however the experts at PRAPeR Meeting 01 (September 2006) considered that the method was not specific to sulfuryl fluoride and established a data gap accordingly.

2. Mammalian toxicity

Sulfuryl fluoride was discussed in the PRAPeR experts' meeting 04 in September 2006.

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

Sulfuryl fluoride is rapidly absorbed via inhalation (absorption estimated to be 14% at 30 ppm and 11% at 300 ppm); it is rapidly excreted, mainly via the urine. Data indicate that sulfuryl fluoride is first hydrolysed to fluorosulfate, with release of fluoride, followed by further hydrolysis to sulfate and release of the remaining fluoride. Increased intake of fluoride may lead to fluorosis.

2.2. Acute toxicity

Sulfuryl fluoride is a gas (the main exposure route is via inhalation). A complete acute toxicity data package is missing (eye and skin irritation tests were not performed) and a skin sensitisation study was not conducted. However, experience in humans over a period of 40 years of use of the formulation "Vikane" indicates that sulfuryl fluoride is not an eye irritant, or a skin sensitiser. Sulfuryl fluoride has been classified (29th ATP, Commission Directive 2005/73/EC⁸) as T; R23 'Toxic by inhalation' based on reported deaths in humans. In rat and guinea pig oral studies (of limited validity) the LD50 was 100 mg/kg bw. In the experts' meeting the risk phrase T; R25 'Toxic if swallowed' was proposed. The experts' meeting proposed in addition the classification as Xi; R37 'Irritating to the respiratory system'.

2.3. Short term toxicity

Sulfuryl fluoride has been studied for inhalation toxicity in rats, dogs, mice and rabbits. Effects after inhalation included necrosis and vacuolation in the cerebrum of rabbits, lung inflammation and tremors in dogs, and mild renal changes in rats. In mice and rabbits the relevant NOAEL is 30 ppm, while in dogs the NOAEL is 20 ppm based on respiratory tract inflammation at 80 ppm. In the rat, the relevant NOAEL is 100 ppm based on renal hyperplasia at 300 ppm. Dental fluorosis was one of the most sensitive effects in some studies, in most cases with no histopathological correlate. In the experts' meeting it was agreed that very mild to mild dental fluorosis is not an adverse effect. It was noted that in an EFSA Opinion (Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride, EFSA-Q-2003-018, adopted on 22 February 2005 (EFSA 2005)) a limit value is presented for the fluoride ion for children.

Sulfuryl fluoride is classified in the EU as Harmful; R48/20 'Danger of serious damage to health by prolonged exposure/inhalation route'.

⁸ OJ L 216, 16.6.2004

2.4. Genotoxicity

Sulfuryl fluoride showed no genotoxic potential in *in vitro* tests for bacterial cell mutation or mammalian DNA repair, but was positive in the *in vitro* tests for mutagenicity and clastogenicity in mammalian cells; the *in vivo* micronucleus test showed negative results.

During the experts' meeting, it was discussed that the positive results might be linked to the fluoride ion. It was noted that the Commission proposed inclusion in Annex I of the biocide directive, with no indication of genotoxicity.

The experts agreed on no genotoxic potential for this substance.

2.5. Long term toxicity

In male and female rats and mice the long-term NOAEL was 20 ppm, based on chronic progressive glomerular nephrosis and respiratory irritation in male and female rats, and histopathological changes in the brain (vacuolation) and thyroid glands of male and female mice at 80 ppm. Sulfuryl fluoride did not show tumourigenic or carcinogenic potential in male or female rats or mice at any of the exposure levels up to and including 80 ppm.

2.6. Reproductive toxicity

Sulfuryl fluoride had no effect on reproductive parameters when inhaled by rats in a 2-generation study for 6 hours/day, 5 - 7 days a week for up to 20 consecutive weeks. At 20 ppm parental animals showed an increased incidence of aggregates of alveolar macrophages in F0 and F1; at 150 ppm reduced bodyweights, dental fluorosis, alveolar macrophages and brain vacuolation were registered. At 150 ppm the only effect in offspring was reduced bodyweight gain in F1 and F2 pups during the lactation period. The parental NOAEL was 5 ppm based on the effects in adult F0 and F1 males and females at 20 ppm; the NOAEL in offspring was 20 ppm based on reduced growth during lactation at 150 ppm. It was concluded that sulfuryl fluoride is not teratogenic in either rats or rabbits. The relevant parental and developmental NOAEL is 75 ppm from the rabbit study.

2.7. Neurotoxicity

Sulfuryl fluoride was tested for neurotoxicity in rats in an acute inhalation study, a 13-week inhalation study, and a 1-year inhalation study in rats. No effect on evoked potentials occurred at 300 ppm, which was the NOAEL for the acute study in rats. In the 13-week study female rats showed visual and somatosensory evoked potentials significantly slower, while in males auditory brainstem responses were slower at 100 ppm. At 300 ppm mild vacuolation of the brain in the central or peripheral nervous system was evident. The NOAEL in this study was 30 ppm. The 1-year neurotoxicity study in male and female rats included a FOB, motor activity tests, fore- and hindlimb grip strength, hindlimb landing foot splay and neurohistopathology with perfusion fixation. There were no effects on the nervous system at the highest concentration tested. The NOAEL was 80 ppm.

2.8. Further studies

No mechanistic study provided.

2.9. Medical data

Sulfuryl fluoride has been used as a structural fumigant since the 1960s. Manufacturing plant health surveillance examinations revealed no significant sulfuryl fluoride-related health problems among employees. In the USA, 335 reports of human health effects associated with the use of "Vikane" have been reported to the U.S. EPA by the applicant since 1993. There were 13 human deaths, primarily resulting from unauthorized re-entry into fumigated structures. In many cases, incidents involved symptoms of eye and respiratory irritation, sore throat and cough, which may have been related to residual chloropicrin, a warning agent with "Vikane". Other effects included flu-like symptoms of nausea, diarrhoea, fever and headache, shortness of breath or respiratory distress.

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

Acceptable Daily Intake (ADI)

The relevant NOAEL from the 2-year rat study is 20 ppm based on effects on the kidneys. Based on inhalational estimates of 10% and a safety factor of 100, the RMS proposed an ADI of 0.02 mg/kg bw/day. During the experts' meeting the correction factor of 5/7 (5 days exposure) proposed by the RMS was discussed, which would lower the value from 0.02 mg/kg bw/day to 0.014 mg/kg bw/day. JMPR proposed a value of 0.01 mg/kg bw/day, based on 2-year rat study and a 2-generation rat study, and applying a safety factor of 100.

The value of 0.014 mg/kg bw/day was agreed, with a safety factor of 100, based on the long-term toxicity study in rats⁹. The proposed ADI of 0.014 mg sulfuryl fluoride/kg bw/day is equivalent to an intake of 0.005 mg fluoride/kg bw/day.

Acute Reference Dose (ARfD)

Sulfuryl fluoride

The most relevant assay was the acute neurotoxicity study, showing a NOAEL of 300 ppm, equivalent to 60 mg/kg bw/hour. Using a correction factor of 0.1 to account for estimated inhalation, and applying a 100-fold safety factor, the experts agreed on an ARfD of 0.7 mg/kg bw. The proposed ARfD of 0.7 mg sulfuryl fluoride/kg bw is equivalent to an intake of 0.25 mg fluoride/kg bw.

Fluoride

In the experts' meeting the ADI and ARfD for the fluoride were discussed as well. An ADI of 0.005 mg/kg bw/day has been calculated on the basis of the parent compound, taking into account the molecular weight. A value has been established in the EFSA Opinion (EFSA, 2005) for children up to 8 years, based on human data, resulting in 0.1 mg/kg bw. It was discussed whether an appropriate value could be derived from the EFSA Opinion. At the moment no scientifically based conclusion can be drawn on the ADI and ARfD for the metabolite. The point remained open for the metabolite.

Acceptable Operator Exposure Concentration (AOEC)

Working practice in the UK indicates that exposure to sulfuryl fluoride is at worst case on two consecutive weekends (this is the only time when mills are fumigated to limit 'down-time'). During the experts' meeting it was considered that an occupational safety value is available from Germany of 21 mg/m², while the AOEC from the national registration in Italy is 3 ppm, in France 2 ppm, in Germany 2.4 ppm, and in the United Kingdom 3 ppm.

The exposure is mainly re-entry exposure due to the application technique. The application is only done by professionals and re-entry is only allowed after a certain decrease of the substance is measured.

During the biocide evaluation an AOEC of 1 ppm was based on the 90-day mouse inhalation study with a safety factor of 100. It was proposed by some Member States to develop the values in line with the biocide evaluation, and to base the values on short-term studies in rats and dog, reporting a NOAEL of 100 ppm; applying a safety factor of 100, the AOEC resulted in 1 ppm. This was agreed. For the bystander an AOEC of 3 ppm was considered sufficient.

⁹ Method of calculation:

ppm = mg/m³ × 24.45/gram molecular weight, where 24.45 is the molar volume of air in litres at normal temperature and pressure (NTP - 25° C and 760 mm Hg). The gram molecular weight of sulfuryl fluoride is 102.1, hence:

1 ppm = 102.1/24.45 = 4.1759 mg/m³, or 0.0042 mg/L

1 ppm SF = 0.0042 mg/L; 20 ppm = 0.0042 mg/L × 20 ppm = 0.084 mg/L

Rat breathing rate = 45 L/kg bw/hour (EU Guidance 7531/VI/95 rev.6); Inhaled dose = 0.084 mg/L × 45 L/kg bw/hour = 3.78 mg/kg bw/hour. Study exposure period was 6 hours/day = 6 hours × 3.78 mg/kg bw/hour = 22.68 mg/kg bw/day

Inhalation absorption = 10% (PSD default value for SF) = 22.68 mg/kg bw/day × 0.1 = 2.268 mg/kg bw/day

Safety factor = 100 (default for ADI based on animal NOAEL)

Correction for 71% (5 days exposure out of 7)

Signs of local respiratory irritation at very low dose levels in the short-term and reproduction toxicity studies were not considered for risk assessment (reference doses) because the formulation will be applied by trained operators only, wearing appropriate PPE including a mask. Additional classification and labelling with R37 'Irritating to the respiratory system' was deemed necessary.

2.11. Dermal absorption

No data were submitted (the active substance is a fumigant).

2.12. Exposure to operators, workers and bystanders

The applicant submitted exposure studies performed in the UK, Germany, Italy and the US to support approval. A total of eight studies were performed, comprising 7 different mills in 11 individual fumigation trials. All studies were performed according to GLP.

The exposure studies monitored levels of potential inhalation exposure for operators, bystanders and re-entry workers. Exposure to operators (fumigators) was determined by monitoring the atmospheric concentration of sulfuryl fluoride in their breathing zone using personal air samplers whilst they performed various work tasks. Potential bystander exposure was determined by continuous air sampling at various distances and directions from the mill during fumigation and aeration. Exposure to workers re-entering the mill after it had been declared safe for re-entry (internal sulfuryl fluoride concentrations were <5ppm) was determined by continuous air sampling at various locations within the mill.

Due to the modified AOEC value, the RMS was asked to revise the operator exposure assessment. The new assessment was not peer reviewed or discussed in an experts' meeting.

Comparison of the maximum 8-hour time-weighted average (TWA) results with the AOEC of 1 ppm, shows a number of exposures are above this value (9/17) (the highest 8-hour TWA being 4.2 ppm, based on a single measurement of 17.2 ppm over 117 minutes exposure period (Ref. SCFM US, p.448 Vol.3 Annex B, Appendix 4.1). This measurement resulted from a study where the fumigators were involved in the evaluation of achievable release rates for sulfuryl fluoride, a practice which involved the frequent disconnection and re-connection of the shooting lines from the cylinders. The RMS stated that this practice does not represent typical commercial practice and may explain these high results. None of the calculated exposure levels consider the use of suitable respiratory protective equipment. Therefore, the RMS concluded that operators introducing fumigant or carrying out tasks associated with the aeration procedure should wear suitable respiratory protective equipment when handling or applying fumigant. When working in the adjacent spaces where it is considered the fumigant could occur at concentrations above acceptable levels the fumigator must either move away from the area or wear self-contained breathing apparatus (SCBA) whenever air concentrations exceed 1 ppm.

Based on the available data, a 10-metre exclusion zone around the fumigated structure is considered to protect unprotected persons (i.e. bystanders) from levels of sulfuryl fluoride above 3 ppm.

For unprotected persons re-entering a fumigated structure after analytical equipment has confirmed it is clear for re-occupation, the available data suggest sulfuryl fluoride levels will be below 1 ppm (TWA for 8-hour period post-aeration). However, it is possible that localised sulfuryl fluoride concentrations can remain high after the rest of the mill is safe for re-occupation. Persons re-entering a fumigated structure after aeration must therefore wear SCBA until sulfuryl fluoride levels in all areas of the mill have been confirmed to be safe.

The possibility of adding an "alert" substance to sulfuryl fluoride was discussed in the meeting, even if some Member States considered this extremely difficult due to the physical/chemical characteristics of the active substance (the possibility was already considered at Member State level for national authorization with no success).

3. Residues

Initially the applicant proposed the representative uses as structural fumigation of an empty flour mill and grain stores, fumigation of dried fruit (such as raisins, prunes and apricots), and fumigation of tree nuts (e.g. walnuts, almonds, pistachios). Due to lack of data and the resulting uncertainties in the risk assessment identified during the peer review the applicant agreed to the RMS' proposal to withdraw the food uses from the evaluation for the Annex I inclusion of sulfuryl fluoride. The applicant announced that these uses will be pursued later at Member State level. Therefore, the only remaining use for Annex I inclusion is the structural treatment of empty grain stores and flour mills. However, for the sake of transparency knowledge gained during the peer review concerning the use of sulfuryl fluoride in food commodities is presented in this conclusion where possible.

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

Metabolism studies were not submitted to support the initially proposed fumigation of food commodities. However, the chemical fate of sulfuryl fluoride in food commodities was reported in a published paper, referenced by the applicant. The paper (Meikle, 1964)¹⁰ is based on a qualitative distribution study in whole wheat flour fumigated with radio-labelled sulfuryl-S³⁵-fluoride.

The findings reported in the paper indicated that the fumigated flour contained non-volatile alteration products. 76% of the TRR could be extracted from the flour and were further investigated by column and paper chromatography techniques. The residues were attributed to molecules with anionic character. Subsequent hydrolysis and chromatography steps indicated the presence of different amino acids, and the author presumed that this could only arise from polypeptide molecules as present in e.g. the gliadin protein of wheat. In addition, radioactive sulfate was detected. Sulfate is formed as a result of conventional hydrolysis of sulfuryl fluoride. The unextractable residue (24% TRR) was in some way fixed to the protein fraction of the residue and not further identified. The results suggested that the radioactivity in whole wheat flour after sulfuryl-S³⁵-fluoride fumigation is present in the form of sulfate and as products resulting from a chemical reaction of sulfuryl fluoride with N-terminal free amino groups on amino acids.

As there was no radiolabel in the fluorine, the fate of the fluorine part of the molecule could not be investigated. With reference to another paper (Meikle & Stewart, 1962)¹¹ the author concluded that an additional product resulting from the sulfuryl fluoride breakdown reaction in wheat flour would be inorganic fluoride.

Additionally, a study on the determination of levels of sulfuryl fluoride, sulfate (SO₄²⁻) and fluoride (F⁻) residues upon fumigation of different matrices with unlabelled substance (e.g. wheat flour, dry milk, dried beef, vegetable oil, apples) was submitted. Vegetable oil desorbed the greatest quantity of residual sulfuryl fluoride of all commodities tested, but was virtually free of anionic residues. Maximum inorganic fluoride residues were observed in dried beef and maximum sulfate residues in dry milk. Apparently, the composition of the food matrix (e.g. protein and oil content) and physical conditions (e.g. surface area and texture) affected the partitioning behaviour and the propensity for degradation of sulfuryl fluoride. It was also found that fluoride and sulfate residue concentrations did not correlate with sulfuryl fluoride exposure concentrations, and that the duration of the aeration period after treatment had no effect on the fluoride and sulfate residue levels.

The applicant stated that the breakdown pathway of sulfuryl fluoride proceeded via a non-metabolic pathway and would be therefore identical in all matrices. The available information would indicate that sulfuryl fluoride rapidly penetrated all tested matrices, reacting primarily with free amino groups

¹⁰ R. W. Meikle, The Dow Chemical Co. , Journal of Agricultural and Food Chemistry, Vol. 12, No.5, 464(1964)

¹¹ R. W. Meikle and D. Stewart, The Dow Chemical Co. , Journal of Agricultural and Food Chemistry, Vol. 10, No.5, 393 (1962)

of amino acids and proteins via nucleophilic substitution reactions. Any unreacted sulfuryl fluoride present in the matrix is in most cases rapidly displaced on aeration, leaving only fluoride and sulfate as the terminal residues. If sulfuryl fluoride is degraded by conventional hydrolysis in the presence of acids and bases then fluorosulfonic acid is created as an intermediate. This direct hydrolysis product fluorosulfonic acid is considered in the environmental risk assessment (refer to section 4). Whether fluorosulfonic acid residues may be pertinent to food residues was not addressed by the information provided and assessed.

The experts in PRAPeR 05 discussed whether the metabolism or mode of degradation respectively, of sulfuryl fluoride in food and feed commodities was sufficiently investigated, and whether there was satisfactory proof that the proposed breakdown mechanism is identical in all matrices, as suggested by the applicant. At the time of the meeting the experts concluded that the available information was not sufficient to assess the involved reactions and to verify the reported results. The acceptability and scientific standard of the study with radio-labelled sulfuryl-S³⁵-fluoride could not be discussed based on a study summary only. Data gaps for submission of the referenced study report with radio-labelled sulfuryl-S³⁵-fluoride, and clarification of whether protein-bound fluoride is bio-available under physiological conditions were identified. Moreover, the fate of fluorinated amino acids entering the organism and the potential for accumulation of fluorocarbon structures in body tissue should be addressed by the applicant.

EFSA notes that many assumptions made in the paper (Meikle, 1964) are not supported by experimental data. Though the experiments might have been conducted according to modern standards in the 1960s, from the current point of view the paper is considered to be of low to medium quality in terms of its use in consumer risk assessment. EFSA suggests carrying out a study according to modern standards in order to fully elucidate the nature of the residues in food matrices upon fumigation with sulfuryl fluoride. From research papers it is known that, due to its small steric size, fluorine has been used as a replacement for hydrogen in many biologically active molecules, including amino acids. Once introduced, the strong carbon-fluorine bond is particularly resistant to metabolic transformations, and the electro-negativity of fluorine can have a significant effect on the basicity and acidity of neighbouring groups and on the electron distribution, and can change the overall reactivity and stability of the molecule.^{12 13 14}

After the experts' meeting, the RMS indicated that they do not agree with the data gaps proposed by the experts and that with regard to the remaining notified uses, in particular flour mills, no further data will be necessary if appropriate mitigation measures against contamination are adopted. However, the EFSA believes that for all uses where sulfuryl fluoride can come into contact with food (directly or through contamination) data on the nature and levels of the residue should be required for the risk assessment. Only if these data are available can it be adequately assessed which measures are appropriate to mitigate consumer risk.

Provisionally, a residue definition for risk assessment and monitoring was proposed to include sulfuryl fluoride on one hand and inorganic fluoride on the other hand. The experts agreed that, if protein-bound fluoride can in some way be taken up by the consumer, it should also be included in the residue definition.

Three residue trials carried out in flour mills (UK, Germany, and the USA, 2002) support the proposed GAP. Residues of sulfuryl fluoride in flour and bran were not determined in the GAP trials. A case was made that a study on the effect of fumigation variables on the residue levels (2000) indicated residues of less than 0.008 mg/kg in flour and bran after fumigation (apart from one experiment which gave a positive residue of 0.008 mg/kg at the intended concentration and time). It is noted that in the study the commodities were placed in the fumigation chamber always in secondary containers.

¹² Welch, T.S. and Eswarakrishnan, S.: Fluorine in Bioorganic Chemistry, John Wiley and Sons, New York, 1991

¹³ Harper, D.B. and O'Hagan, Nat. Prod. Rep., 1994, **11**, 123

¹⁴ Sutherland, A. and Willis, C.L.: Synthesis of fluorinated amino acids. Nat. Prod. Rep., 2000, **17**, 621-631

Samples were taken from the mid-level of the fumigated commodity. According to the applicant the study design would not have inhibited the formation of residues in the samples. Hence, only fluoride was determined in the GAP residue trials conducted in flour mills.

It is noted that the LOQ in the analytical method for fluoride used in these trials was relatively high (2 mg/kg for flour, nuts, dried fruit; 4 mg/kg bran). The applicant indicated that meanwhile the method for the determination of fluoride in flour has been validated down to 0.5 mg/kg. To be able to confirm that consumer exposure to fluoride residues in flour produced after an appropriate pre-production period will not be higher than to naturally occurring background levels, a lower LOQ than 2 mg/kg was considered necessary. The trials indicate that residues of fluoride in the flour and bran fell below 2 mg/kg flour and 4 mg/kg bran (respective LOQs in the trials) after 60 minutes of full production (following a pre-production period), with the exception of one flour sample, which still contained a residue of 2.7 mg/kg. Residues in flour and bran directly after re-initiation of the full production were found to be significantly higher than the results reported at 60 minutes of full production.

Given the findings in the residue trials it is assumed that a longer period than one hour of full production may be necessary to reach natural background levels (examples from public literature: rye flour approx. 50-60 µg/100g, wheat flour 12-60 µg/100g, depending on flour type, wheat bran 156 µg/100g)¹⁵.

It is noted that the applicant made a case for only disposing of the first 10 minutes of full production, and for dilution of contaminated flour after 10 minutes production with the flour produced after one hour in order to reduce residues below 2 mg/kg, due to the disposal of the first hour's production being unworkable from an economic point of view. This case is not supported by data on the actual residue levels when the proposed procedure is applied. It is also noted that there are certain prohibitions on the practice of processing and/or mixing products for dilution purposes imposed in the framework of the MRL Regulation (Article 19 of Regulation (EC) No. 396/2005¹⁶ refers). If such a procedure should reflect common practice in commercial production, trials should be submitted, to address the level of residues resulting from this practice, and representing the range of different flour mill plants found across Europe. Moreover, there are currently no agreed acceptable fluoride background levels, and therefore the level of 2 mg/kg used in the applicant's case appears to be arbitrary. It is noted that the RMS has proposed in the DAR a confirmatory data requirement: Flour, bran, wheat germ and wheat feed samples to be taken and analysed for fluoride from four commercially fumigated flour mills. The flour, bran and wheat germ samples must be taken from the first batches produced by the mill, to ensure that reprocessing results in residues of fluoride in the flour, bran and wheat germ below the limit of quantification.

It is acknowledged that measures to ensure that food or feed contaminated above natural background levels will not enter the food chain are clearly a risk management issue. However, it should be noted that during the peer review procedure different Member States raised their concerns about the feasibility and acceptability of the proposed re-processing and dilution measures.

No residue data were submitted to support the use in grain stores since according to the GAP the grain stores have to be empty during fumigation, and no contamination of grain should occur during or after a treatment with sulfuryl fluoride.

Residue trials in tree nuts (pistachios, pecans and almonds) and dried fruit (dates, figs and plums) were also submitted. However, these trials were only small scale trials. Therefore, residue studies to simulate the commercial treatment, i.e. fumigation of large containers or stacks with greater propensity for dead spaces and therefore potentially higher residue levels, need to be carried out. For Annex I inclusion of sulfuryl fluoride these uses are no longer supported by the applicant.

¹⁵ Souci, S. W.; Fachmann, W.; Kraut, H.: Food composition and nutrition tables. Wissenschaftliche Verlagsges.mbh, Stuttgart, 2000

¹⁶ OJ L 70, 16.03.2005, p.11

No processing data were submitted or required as none of the food commodities intended to be directly fumigated is further processed.

3.1.2. Succeeding and rotational crops

Sulfuryl fluoride is not used on crops in the field, and therefore potential uptake of residues by succeeding and rotational crops is not relevant.

3.2. Nature and magnitude of residues in livestock

No data were submitted to assess the fate of residues resulting from the use of sulfuryl fluoride when products with residues, e.g. cereal products are fed to livestock. Further investigation of this issue may not be relevant as in theory no residues are expected to occur on potential feed items as a result of the requested representative uses (empty grain store and mill treatments). Flour and bran milled in the pre-production run and in the first time of full production, which are contaminated and are supposed to be separated from the remaining production, must not be fed to livestock animals.

Concerning the withdrawn representative uses on dried fruits and nuts, no livestock exposure was expected since these commodities are not usually fed to animals.

For summary information on animal exposure to fluorine the reader is referred to the EFSA Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to Fluorine as undesirable substance in animal feed, EFSA-Q-2003-034, adopted on 22 September 2004 (EFSA, 2004).

3.3. Consumer risk assessment

The residues relevant for the consumer exposure risk assessment were preliminary identified as sulfuryl fluoride and fluoride. Whether or not protein-bound fluoride (or other fluoride containing compounds originating from sulfuryl fluoride degradation) also has to be included in the assessment needs to be determined upon receipt of the information and data requested by the experts of the PRAPeR 05 meeting. Therefore, the consumer risk assessment cannot be finalised for uses where sulfuryl fluoride comes into contact with food (directly or by contamination).

Even though the representative uses are empty structure treatments (mills and grain stores), it is noted that a possible source of consumer exposure is through contaminated flour and bran that remained in the mill machinery during fumigation and, according to the applicant, passive co-fumigation of the grain stored in silos in the mill may also be possible. Available data show that high fluoride residue levels in flour and bran occurred after the production in a treated mill structure had been taken up again, and thus measures to avoid contaminated cereal products getting into the food chain are necessary. Such risk management measures, e.g. disposal of production until natural background levels are reached, or other restrictions for mill treatments, should be dealt with at Member State level to cover the potential for contamination ('passive co-fumigation'). However, currently there is insufficient information or data submitted to allow a conclusion to be made on the details of such proposed mitigation measures (e.g. amount of produce to be discarded until background levels are reached and/or time of production or re-processing needed to reach fluoride background levels in flour and bran).

It is also noted that in a consumer risk assessment not only the exposure to fluoride residues from the use of sulfuryl fluoride needs to be considered, but all sources of fluoride exposure.¹⁷ In order to conclude whether the additional contribution from the use of sulfuryl fluoride to the overall fluoride exposure does not put the consumer at risk, an aggregate risk assessment needs to be carried out.

¹⁷ Ref. to the EFSA opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride. (EFSA, 2005)

The experts' meeting PRAPeR 05 proposed to refer a question to EFSA concerning the aggregate consumer risk assessment for fluoride with consideration of residues resulting from the use of sulfuryl fluoride. However, due to insufficient data with regard to the envisaged uses a sound assessment would currently not be possible.

For the empty grain store use no consumer exposure to residues of sulfuryl fluoride is expected when applied in accordance with the notified GAP.

3.4. Proposed MRLs

No peer reviewed MRL proposal is available. The RMS proposed the following: No residues of sulfuryl fluoride above the LOQ are expected from fumigation of empty grain stores and flour mills and therefore sulfuryl fluoride MRLs for flour, bran and grain may be proposed at the LOQ of the analytical method for sulfuryl fluoride (0.008 mg/kg). No risk assessment with the proposed MRLs for sulfuryl fluoride was submitted.

Significant residues of fluoride ion can be present from various sources, and separate MRLs for fluoride ion should be proposed based on background levels.

EFSA is not aware that there are agreed acceptable fluoride background levels in food products on a European level. Therefore, it is also not possible to assess the adequacy of setting MRLs at the LOQ of the analytical method for fluoride.

4. Environmental fate and behaviour

This section takes into consideration the information presented by the RMS in the DAR, and the conclusions of the meeting of Member State experts PRAPeR 02 that took place in September 2006. In the first evaluation meeting (September 2005), a number data gaps were identified, many of them formal since the applicant had not provided copies of the scientific papers quoted in the dossier. Most of these papers were submitted before the experts' meeting. Scientific information, not directly provided by the applicant but available to Member State experts, was also considered during the experts' meeting and in this conclusion.

A new addendum 3 (UK, 2009) was received in May 2007 prepared by the RMS based on the information provided by the applicant after the meeting of experts. The information contained in the addendum is not considered to be peer reviewed.

The new assessment provided by the applicant and presented by the RMS in the addendum does not strictly follow the scenario approach proposed by the experts' meeting (only lifetime of 4.5 yr is used and production figures are generally limited to historical records from 1992-2000) and does not take into consideration most recent information available to the scientific community on the occurrence of sulfuryl fluoride in the atmosphere.¹⁸ This information is crucial since it supersedes the information used by the applicant to estimate the atmospheric lifetime of the substance on which most of the fate and behaviour assessment of sulfuryl fluoride is based. Therefore, the EFSA produced an addendum (compiled as part of the Final Addendum (UK, 2009)) to update the calculations presented by the RMS and to complete the assessment as far as possible. Neither the RMS addendum 3 nor the EFSA addendum may be considered to be peer reviewed.

It is noted that this section of the conclusion takes into account information on the fate and behaviour of sulfuryl fluoride (specifically monitored tropospheric concentration) that supersedes the information considered for the decision of inclusion of sulfuryl fluoride as an active substance in biocide product type 8 (wood preservatives) in Annex I of Directive 98/8/EC (Commission Directive 2006/140/EC of

¹⁸ Global Measurements of Atmospheric Sulfuryl Fluoride. Mühle, J.; Harth, C.M.; Salmeh, P.; Miller, B.R.; Weiss, R.F.; Portler, L.W.; Fraser, P.J.; Greally, B.R.; O'Doherty, S. *American Geophysical Union, Fall Meeting 2006, abstract # A53B-0191*.

20 December of 2006, OJ L 414, 30.12.2006 p. 78-80)¹⁹. However, the data in footnote 18 were considered in the draft assessment report of sulfuryl fluoride as an active substance in biocide product type 18 (insecticide) under Directive 98/8/EC (Commission Directive 2009/84/EC of 28 July 2009, OJ L 197, 29.7.2009, p.67)²⁰.

4.1. Fate and behaviour in air

Sulfuryl fluoride is a gas under all environmental conditions (boiling point -54 °C). The vapour pressure is deemed to be high but the reliability of the measured value provided could not be confirmed by the experts' meeting on physical and chemical properties (new data gap identified in PRAPeR 01). However, new data submitted after the experts meeting was considered to be acceptable by EFSA to confirm the reliability of the vapour pressure value used in this risk assessment, although the new data were not peer reviewed.

Global scale assessment

Potential degradation routes for sulfuryl fluoride were analysed in the DAR. Biological degradation in water or soil and the potential uptake and degradation by terrestrial plants were considered to be negligible. No information is available on the potential for photochemical degradation by reaction with OH· or NO₃· radicals or ozone, and this route was also considered negligible. With respect to the direct photolysis, only a lower limit for the photolytic half-life of 2.9 yr was calculated in one published paper (Kozlowski, R. et al. 1982). A more recent calculation based on the S-F thermodynamic bond dissociation energy was quoted in the DAR and the summary dossier but the original study was not available in the dossier. A data gap for this study (Ruiz, J. 2001) was identified in the first evaluation meeting. The study was provided to the RMS and its results were discussed in the experts' meeting. The experts concluded that sulfuryl fluoride should be considered as photolytically stable in the troposphere. At the time of finalising this conclusion, new theoretical studies on the atmospheric chemistry of sulfuryl fluoride, published in the scientific literature, confirm the very long chemical lifetimes expected for sulfuryl fluoride in all parts of the lower atmosphere.²¹

The only demonstrated route of dissipation and degradation of sulfuryl fluoride is the chemical hydrolysis that may occur in ocean waters (see section 4.2.1. for details).

In the initial assessment presented in the DAR, fate and behaviour in the atmosphere was based on the presumed no detection of sulfuryl fluoride in a troposphere monitoring programme performed with methods estimated to detect sulfuryl fluoride down to the level of 0.5 ppt. Based on this value, on the historical production and sales data for years 1992 – 2000, and on the assumption that the steady state has been reached, the applicant calculated an atmospheric lifetime of 4.5 yr (corresponding to a half-life of 3.2 yr). However, during the peer review commenting period it was noted that no result published in the quoted scientific literature supported these figures, and a data gap was identified. The applicant clarified that the value for the atmospheric concentration and the limit of detection of sulfuryl fluoride had been obtained directly from a personal communication (e-mail 18-10-2005 answering a query of the Canadian authorities) from the University of California, Irvine (USA). A copy of this e-mail was submitted to the RMS. The experts' meeting considered that the data provided were not reliable enough for regulatory purposes, and identified a data gap for the determination of atmospheric lifetime.

¹⁹ Assessment report for the active substance sulfuryl fluoride (PT8). Finalised in the Standing Committee on Biocidal Products at its meeting on 8 September 2006 in view of its inclusion in Annex I to Directive 98/8/EC. http://ecb.jrc.ec.europa.eu/documents/Biocides/ANNEX_I/ASSESSMENT_REPORTS/AnnexI_AR_2699-79-8_PT08_en.pdf

²⁰ Assessment report for the active substance sulfuryl fluoride (PT18). Finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC. http://ecb.jrc.ec.europa.eu/documents/Biocides/ANNEX_I/ASSESSMENT_REPORTS/AnnexI_AR_2699-79-8_PT18_en.pdf

²¹ The atmospheric chemistry of sulfuryl fluoride, SO₂F₂. T.J. Dillon, A. Horowitz, and J.N. Crowley. *Atmos. Chem. Phys.*, 8, 1547-1557, 2008.

In a personal communication to the EFSA (e-mail 8.09.2006), Prof. Ray Weiss and Dr. Jens Mühle provided the preliminary results of their sulfuryl fluoride tropospheric baseline measurements, performed during the previous two years at the stations Mace Head (Ireland) and Cape Grim (Tasmania) associated with the AGAGE network.²² Based on their preliminary calibrations, tropospheric concentrations measured at these two stations were 1.0 ppt and 0.9 ppt respectively, with annual growth rates of 0.06 ppt and 0.04 ppt per year. From the measured rise rate and the inter-hemispheric gradient a tropospheric mean lifetime for sulfuryl fluoride of about 15 yr (corresponding to a half-life of 10 yr), and an emission rate of 2×10^9 g / yr were estimated. In their communication, Prof. Weiss and Dr. Mühle stressed the need to make publicly available the production and sales data of sulfuryl fluoride in the context of regulatory authorisations, in order to be able to refine lifetimes calculated on the basis of monitoring data. Since November 2006, the above results are also publicly available in the abstract of a presentation at the fall 2006 annual meeting of the American Geophysical Union.¹⁸ Since steady state has not been reached, the calculation proposed in the DAR (pg 326) is not directly applicable to the more recent observed concentration of sulfuryl fluoride of 0.1 ppt. At the time of finalising this conclusion values previously estimated based on measurements of the AGAGE network have been refined and a longer atmospheric lifetime than previously reported is recently quoted in the scientific literature (36 ± 11 yr).^{23, 25}

In a recent evaluation, the California Environmental Protection Agency estimates an atmospheric lifetime for sulfuryl fluoride of 22 yr (corresponding to a half-life of 13.5 yr) with respect to the dissipation pathway of dissolution and degradation in seawater (the only one considered to contribute significantly to the dissipation in the atmosphere).²⁴

A Level II model (v. 2.1)²⁵ based on Mackay fugacity concept²⁶ was presented by the applicant in the dossier to estimate global scale PEC in the different environmental compartments. Main input parameters for this modelling exercise are release rate (historical and estimated sales including the use as a biocide), solubility in water, vapour pressure, atmospheric half-life and hydrolysis rate in alkaline aqueous media (pH 8). Whereas the approach followed to estimate predicted environmental concentrations at global scale was found acceptable by the experts' meeting, none of the modelling exercises presented in the original dossier and summarized in the DAR were considered reliable. Besides the uncertainties identified for some of the input parameters, it was realised that degradation of sulfuryl fluoride in the ocean surface has been accounted for twice by introducing simultaneously the atmospheric dissipation rate (caused by hydrolysis in the ocean surface) and the hydrolysis rate in the same calculation.

Due to the uncertainties in the estimation of atmospheric half-life of sulfuryl fluoride, and the lack of public information on future release estimates of sulfuryl fluoride²⁷ the meeting of experts agreed a scenario approach based on different hypothetical atmospheric lifetimes (4.5, 15, 50 and 100 yr) and a range of sales estimates including production volumes reported in the DAR (1992 – 2000) and 2, 5 and 10 times as much. Level II fugacity model results need to be calculated according these different scenarios to produce global predicted environmental concentrations to be used to complete the risk assessment. These assumptions should also be used to update the estimation of the global warming potential (GWP) and equivalent CO₂ emissions for sulfuryl fluoride.

²² AGAGE: Advanced Global Atmospheric Gases Experiment (<http://agage.eas.gatech.edu/index.htm>)

²³ **Sulfuryl Fluoride in the Global Atmosphere.** Mühle, J.; Huang, J.; Weiss, R.F.; Prim, R.G.; Miller, B.R.; Salameh, P.K.; Harth, C.M.; Fraser, P.J.; Porter, L.W.; Grealley, B.R.; O'Doherty, S. and Simmonds, P.G. *J. Geophys. Res.*, **114**, D05306, doi:10.1029/2008JD011162.

²⁴ **Sulfuryl fluoride risk characterization document. Volume III. Environmental fate.** Environmental Monitoring Branch. Department of Pesticide Regulation. California Environmental Protection Agency. July 2006. (http://www.cdpr.ca.gov/docs/empm/pubs/tac/tacpdfs/sulfluor/final_rcd_vol3.pdf)

²⁵ Canadian Environmental Modelling Centre (<http://www.trentu.ca/academic/aminss/envmodel/models/VBL2.html>).

²⁶ Mackay, D. 1979, *Environ. Sci. Technol.* **13**(10), 1218.

²⁷ Applicant estimates for future production and sales figures were provided under dossier Doc J and summarized in Annex C of the DAR. The applicant requires this information to be treated as confidential.

New Level II fugacity model calculations were provided to the RMS by the applicant in January 2007 and are summarized in addendum 3. In these calculations only a lifetime of 4.5 yr was considered by the applicant claiming that new monitoring data were not publicly available at the time the new data were prepared. With respect to the production estimates, the applicant considered the historical production data (1992 – 2000) and ten times as much. The applicant communicated to the RMS their wish to keep historical production figures confidential.

In order to provide more updated figures, the EFSA has calculated global PEC in the different environmental compartments with a Level II fugacity model using lifetime (15 yr) and emission figures ($2 \cdot 10^6$ Kg SO_2F_2 / yr) estimated on the basis of recent tropospheric monitoring.¹⁸ These emission figures are not confidential and may be assumed to consider not only the applicant's production but also other potential sources of sulfuryl fluoride. In order to take into account the foreseen increase in the use of SO_2F_2 , the calculation was repeated with a ten-fold emission estimate ($2 \cdot 10^7$ Kg SO_2F_2) in agreement with the experts' meeting requirements (see EFSA addendum). Assuming a continuous release of $2 \cdot 10^6$ Kg SO_2F_2 / yr at the steady state the background concentration of sulfuryl fluoride in the atmosphere will be $4.71 \text{ ng} / \text{m}^3$, this corresponds to a mixing ratio of 1 ppt, which is in agreement with most recent measurements. A ten-fold increase in the production will result in a ten-fold increase of the background level (up to 10 ppt). These values should only be considered as indicative but show a potential for accumulation of sulfuryl fluoride in the atmosphere and reinforce the need for continuous monitoring already identified by the PRAPeR 02 experts' meeting and Commission Directives 2006/140/EC and 2009/84/EC in the context of biocides regulation.

With respect to GWP no updated estimation has been provided by the applicant. The value provided in the DAR (378-fold with respect to CO_2 100 yr horizon GWP) is based on a lifetime < 4.5 yr, and therefore it is an underestimation with respect to more recent observations and needs to be re-calculated. At the time of finalising the conclusion a scientific publication became available reporting an estimation of the GWP of sulfuryl fluoride. In this publication a GWP of 4780 was calculated for the 100 years horizon.²⁸ This value is within the range of the values calculated for other chemicals regulated under the Kyoto protocol agreement (eg HFC-134a: $\text{GWP}_{100} = 1430$; sulphur hexafluoride: $\text{GWP}_{100} = 22800$). Potential contributions of sulfuryl fluoride to the global greenhouse effect will need to be assessed with respect to actual and potential overall amount used as a result of its different applications (pesticide, biocide, insulating gas).

Sulfuryl fluoride is generally considered not to contribute to ozone depletion since it does not contain Cl or Br atoms, and formation of free radicals is not expected.

Field scale assessment

In the vicinity of the treated installations, the concentration of sulfuryl fluoride in air is expected to be higher than that calculated as background levels on a global scale. The best estimate is provided by the monitoring studies in the context of the bystander exposure assessment. The highest unidirectional 24-h TWA air concentration measured around a fumigated structure in Europe was 2.73 ppm (5m distance to the mill), and the overall maximum was 7.02 ppm (equivalent to $29 \text{ mg} / \text{m}^3$ assuming normal conditions) measured in the vicinity of a treated mill in the USA (5m away from the mill after accidental leakage). The latter value has been proposed by the RMS to address the field scale environmental risk assessment for sulfuryl fluoride, as summarized and assessed in addendum 3. This addendum has not been peer reviewed, but views sought during the experts' meeting were considered and the EFSA agrees that the selected value represents a realistic worst case for the concentration of sulfuryl fluoride in air, and may be used in the interim for the ecotoxicology risk assessment.

²⁸ Experimental and Theoretical Study of the Atmospheric Chemistry and Global Warming Potential of SO_2F_2 . Vassileios C. Papadimitriou, R.W. Portmann, David W. Fahey, Jens Mühle, Ray F. Weiss, and James B. Burkholder. J. Phys. Chem. A 2008, 112, 12657-12666.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

Solubility of sulfuryl fluoride in unbuffered water at 20 °C is not negligible (1.04 g/L, 10.19 mol / m³). However, partition to surface water is expected to be low due to the high vapour pressure.

The only experimental data provided by the applicant in relation with the environmental fate and behaviour of sulfuryl fluoride in water are a published hydrolysis study.²⁹ In this study hydrolysis of sulfuryl fluoride was investigated in different pH buffered solutions at temperatures of 0°C, 10°C, 20°C and 25°C. The paper was examined by the experts' meeting, which concluded that available measurements in the acidic range (~ 2.0, ~ 5.9) should be regarded only as approximations. However, the meeting agreed that the values derived from this study could be used for the purpose of this assessment. Based on this study the applicant estimated half-lives of sulfuryl fluoride at pH 9 (20°C, DT₅₀ = 4 min), pH 7 (20°C, DT₅₀ = 6.7 h) and pH 5.9 (25°C, DT₅₀ = 3.1 d). The main products expected to occur as a result of the hydrolysis of sulfuryl fluoride are HSO₃F (fluorosulfuric acid) and HF (fluorhydric acid) and their salts. Eventually, HSO₃F may undergo further hydrolysis to yield H₂SO₄ and additional HF.

No study to investigate aqueous photolysis of sulfuryl fluoride in water has been provided. It is not expected that photolysis contributes to the degradation of sulfuryl fluoride in the aqueous media. A ready biodegradability test is not applicable to sulfuryl fluoride as it is an inorganic compound.

No water sediment study is available for sulfuryl fluoride. Fate and behaviour in the aquatic environment is based on the assumption that the only dissipation routes for sulfuryl fluoride in the aquatic environment are hydrolysis and volatilization.

Global scale assessment

The global predicted environmental concentration in surface water was calculated in the DAR based on the Level II fugacity model already discussed in the air section (section 4.1 refers) and not considered acceptable by the experts' meeting. New Level II calculations were provided by the applicant in January 2007, and were summarized by the RMS in addendum 3. This addendum has not been peer reviewed but the calculations are based on the atmospheric half-life calculated from information already superseded by more recent measurements. As part of the new assessment, the applicant provided an estimation of the contribution of the wet deposition (not considered within the scope of a Level II fugacity model). A very low washout ratio is calculated for sulfuryl fluoride (washout ratio SO₂F₂ = 0.015). The reliability of this value is pending confirmation of the vapour pressure (data gap identified in PRAPeR 01).

In order to provide more updated figures, the EFSA has calculated global PEC in the different environmental compartments with a Level II fugacity model using lifetime (15 yr) and emission figures (2·10⁶ Kg SO₂F₂ / yr) estimated on the basis of recent tropospheric monitoring.¹⁸ In order to take into account the foreseen increase in the use of SO₂F₂, the calculation was repeated with a ten-fold emission estimate (2·10⁷ Kg SO₂F₂), in agreement with experts' meeting requirements (see the EFSA addendum). According to these calculations, the concentration of sulfuryl fluoride in water at the steady state will range from 7.3·10⁻⁵ ng/L to 7.3·10⁻⁴ ng/L. These levels are higher than those calculated by the applicant but still below the levels that could be eventually measured in practice with the best available analytical methodologies. Therefore, the global background concentration of sulfuryl fluoride in water that may be reached as a consequence of its release to the atmosphere at levels up to ten times the current emission estimates may still be considered negligible.

In the DAR no estimation of the global aqueous concentration of the hydrolysis products of sulfuryl fluoride was provided. In addendum 3, the equilibrium global concentration of sulfuryl fluoride in

²⁹ Cady, G.H.; Misra, S. *Inorg. Chem.* **1974**, 13, 837-841

surface water was converted to the corresponding concentrations of the species resulting from hydrolysis (HSO_3F and HF). Besides the fact that the calculation is based on an atmospheric half-life for sulfuryl fluoride already superseded by more recent observations, this approach does not take into account the potential accumulation of hydrolysis products. As no information on the geologic cycle of hydrolysis products is available, potential accumulation in the aquatic environments may not be excluded. When the steady state is reached the total annual emission of sulfuryl fluoride will be balanced with the hydrolysis to HSO_3F and HF in the ocean water. Therefore, it is possible to calculate the net inflow of these compounds at the steady state assuming complete conversion of the annual emissions of sulfuryl fluoride. The EFSA calculated the increment per year in the concentration of HSO_3F and HF based on emissions of $2 \cdot 10^6 \text{ Kg SO}_2\text{F}_2 / \text{yr}$ and the same volume of surface water considered for the purpose of the fugacity model calculations ($2.7 \cdot 10^{16} \text{ m}^3$) (see the EFSA addendum). The estimated annual increment in the concentration for HSO_3F and HF in water will be $7.3 \cdot 10^{-2} \text{ ng/L}$ and $1.4 \cdot 10^{-2} \text{ ng/L}$ per year. This is about four orders of magnitude higher than the values proposed in addendum 3. A ten-fold increase in the emission of sulfuryl fluoride will correspond to a ten-fold increase in the increment of the corresponding concentrations per year. As a worst case scenario, the concentration of sulfuryl fluoride hydrolysis products after ten years of emissions at a rate ten-fold with respect to current estimates will be 7.3 ng/L of HSO_3F and 1.4 ng/L of HF . Background surface water concentrations for fluoride are in the range of 0.01 to 0.3 mg/L ,³⁰ (in sea water the average level has been reported to be higher: 1.3 mg/L).³¹ Therefore, the global increment of fluoride in surface water due to the continuous use of sulfuryl fluoride may be expected to be negligible with respect to naturally occurring background levels. No background levels are available for HSO_3F and no information on the half-life of this compound in water is available. Further information on the fate of HSO_3F in water may be necessary to finalise the risk assessment.

Field scale assessment

No field scale assessment for surface water was provided in the DAR. However, the concentration of sulfuryl fluoride in surface water bodies in the vicinity of treated installations may be expected to be higher than the global background level. The need to perform a field scale aquatic risk assessment for sulfuryl fluoride and its hydrolysis transformation products was confirmed by the experts' meeting.

New calculations are provided in addendum 3. The applicant proposed to calculate PEC_{SW} based on the partition resulting from the application of the Henry's Law constant. The RMS re-calculated this PEC_{SW} using the worst case air concentration observed in monitoring studies in the vicinity of the treated structures (7.02 ppm). This resulted in a maximum PEC_{SW} of $0.459 \text{ } \mu\text{g/L}$ for a static water body at 5m distance from the treated installation. This calculation has not been peer reviewed, however the EFSA agrees that the calculated value represents a realistic worst case for the concentration of sulfuryl fluoride in surface water.

No field scale PEC_{SW} for the hydrolysis transformation products HSO_3F and HF are provided in addendum 3. Conversion of the calculated sulfuryl fluoride PEC_{SW} for the molecular weight of the transformation products results in surface water concentrations of $0.45 \text{ } \mu\text{g/L}$ and of $0.09 \text{ } \mu\text{g/L}$ for HSO_3F and HF respectively (assuming 100% transformation of parent compound to each metabolite). However, these estimates do not consider any dynamic process. The hydrolysis rate of sulfuryl fluoride is pH dependent, being relatively fast at alkaline pH ($\text{DT}_{50 \text{ pH } 8.1} = 0.68 \text{ h}$). The PEC_{SW} of sulfuryl fluoride is estimated on the basis of 24 h TWA air concentrations. During this 24 h interval a number of complete hydrolysis cycles may occur, which will result in higher surface water concentrations of the hydrolysis products. Other dynamic processes, such as slow diffusion rates, could eventually counter-balance the rapid hydrolysis. Additionally, it is expected that HSO_3F in water will undergo hydrolysis to a large extent. Further information would be needed to conclude on the field scale surface water assessment for hydrolysis transformation products of sulfuryl fluoride.

³⁰ [Environmental Health Criteria 227: Fluorides](#). World Health Organization, 2002, page 38.

³¹ [Fluoride in Drinking-water: Background document for development of WHO Guidelines for Drinking-water Quality](#). World Health Organization, 2004, page 2. and herein: Sloof W., *et al.* eds. (1988) *Basisdocument fluoriden*. Bilthoven, Netherlands, National Institute of Public Health and Environmental Protection (Report No. 758474005).

Additionally, further assessment would be needed to address the potential acidification of static water bodies in the vicinity of installations repeatedly treated over a long period of time.

4.3. Fate and behaviour in soil

4.3.1. Route and rate of degradation in soil

No experimental data on the fate and behaviour of sulfuryl fluoride or its transformation products in soil were submitted in the dossier. After treatment, the building will be vented directly to the atmosphere. For the proposed uses (treatment of empty storage and milling facilities) exposure of natural soils may only be produced by partition from the atmosphere and through wet deposition through products solved in rain. No experimental data to calculate the rate of degradation of sulfuryl fluoride in soil are available in the dossier. Standard degradation studies in soil are not applicable to sulfuryl fluoride, however it may be envisaged that dissipation may be rapid due to re-volatilization and hydrolysis in soil water to HSO_3F and HF . Therefore, soils could eventually be contaminated by the parent sulfuryl fluoride and its atmospheric and hydrolysis degradation products.

Global scale assessment

Only the potential contamination by the parent sulfuryl fluoride was addressed in the dossier based on the fugacity model calculation that was considered not acceptable by the experts' meeting (see section 4.1).

New PEC_s for sulfuryl fluoride have been calculated in addendum 3. These values are not peer reviewed but have been obtained with a Level II fugacity calculation using the atmospheric half-life already superseded by recent monitoring measurements. In order to provide updated figures, the EFSA has calculated global PEC in the different environmental compartments with a Level II fugacity model using lifetime (15 yr) and emission figures ($2 \cdot 10^6 \text{ Kg SO}_2\text{F}_2 / \text{yr}$) estimated on the basis of recent tropospheric monitoring.¹⁸ In order to take into account the foreseen increase in the use of SO_2F_2 , the calculation was repeated with a ten-fold emission estimate ($2 \cdot 10^7 \text{ Kg SO}_2\text{F}_2$), in agreement with experts' meeting requirements (see the EFSA addendum). At the steady state, global PEC soil will range from $8.3 \cdot 10^{-7}$ to $8.3 \cdot 10^{-6} \text{ ng SO}_2\text{F}_2 / \text{Kg}_{\text{soil}}$. These levels may be considered negligible in practice. However, the applicability of the Level II fugacity model to derive meaningful PECs in soil is considered disputable by EFSA. The Level II model soil concentration derives only from the partition to soil organic carbon content. In this sense the soil is assumed to be dry. The standard environmental assessment is based on wet soils. Therefore, SO_2F_2 partitioned to the soil water would need to be added to the calculated concentrations.

As part of the new assessment presented in addendum 3, the applicant provided an estimation of the contribution of the wet deposition (not considered within the scope of a Level II fugacity model). A very low washout ratio has been calculated for sulfuryl fluoride (washout ratio $\text{SO}_2\text{F}_2 = 0.015$). The reliability of this value is pending confirmation of the vapour pressure (data gap identified in PRAPeR 01). Furthermore, the applicant states that since rain water is acidic (approx $\text{pH} = 5.6$) and the average atmospheric temperature is low (15°C) potential hydrolysis of sulfuryl fluoride in the atmospheric water would be much slower ($\text{DT}_{50} = 10.4 \text{ d}$) than average transit times for rain drops. Therefore, only parent flux of sulfuryl fluoride to soil as a result of wet deposition is calculated in this new assessment. However, this estimation uses as a starting point a PEC_{AIR} that was disregarded as an underestimation by the experts' meeting. The RMS re-calculated in addendum 3 the flux value based on the new PEC_{AIR} obtained with the now superseded atmospheric half-life of 3.2 yr. Finally, using the PEC_{AIR} obtained assuming an atmospheric half-life of 10 yr, the EFSA has re-calculated a flux range of $7.0 \cdot 10^{12} - 7.0 \cdot 10^{11} \text{ g} / \text{m}^2 \cdot \text{yr}$ (see the EFSA addendum).

A worst case estimate for the global PEC_s for HSO_3F and HF may be calculated assuming complete conversion of the wet deposition of sulfuryl fluoride to these transformation products. Since the dissipation rates in soil for these two compounds are not known the range for PEC_s after ten year accumulation in a 5 cm soil layer without dissipation has been calculated to represent an extreme worst case. Under these assumptions, accumulated PEC_s for HSO_3F will be $9.1 \cdot 10^{-4} - 9.1 \cdot 10^{-3} \text{ ng}$

HSO_3F / Kg_{soil} and PEC_s for HF will be $1.8 \cdot 10^{-4} - 1.8 \cdot 10^{-3} \text{ ng HF} / \text{Kg}_{\text{soil}}$ (see the EFSA addendum, these values are 8 to 9 orders of magnitude higher than those estimated in addendum 3). Global PEC_{soil} of HF as a result of the sulfuryl fluoride use is negligible with respect to background levels of fluoride in soil ($73 - 566 \mu\text{g F}^- / \text{Kg soil}$).³² No background levels are available for HSO_3F , however, the levels calculated assuming extreme worst case conditions are lower than those that could be measured with the best available analytical technology. Additionally, it is expected that HSO_3F will dissipate in soil and undergo hydrolysis to a large extent.

Field scale assessment

In the DAR, information on possible concentrations of sulfuryl fluoride at field scale in soil was not available. A Level I fugacity model calculation was provided for the experts' meeting. The experts' meeting realized that the results were not congruent with previous results (concentrations lower than the ones calculated at global scale) and found the calculation to be not acceptable. The experts' meeting confirmed the need to address potential soil contamination at field scale by sulfuryl fluoride and its hydrolysis transformation products.

A new Level I fugacity calculation has been provided by the applicant, and is summarized by the RMS in addendum 3. The sensitivity of the model to arbitrary input parameters, such as the volume of the different environmental compartments, needs to be assessed. In particular, the EFSA noted that the volume of air intended to be represented is miscalculated (it should be $3.14 \cdot 10^7 \text{ m}^3$ instead of $3.14 \cdot 10^5 \text{ m}^3$, therefore the air compartment has been assumed to be 10 m high instead of 1000 m high in the calculation provided). The depth of the soil layer in equilibrium with air, and the density of soil may need to be reconsidered in accordance with standard PEC_s calculations. In addition, the contribution of partition to the soil moisture needs to be considered (see the EFSA addendum). The EFSA recalculated the Level I fugacity model with a soil depth of 5 cm, an air compartment 1m high, and a soil density of 1.5 g/cm^3 . The result of this calculation is factually identical to that provided in addendum 3 ($5.09 \cdot 10^{-3} \text{ ng SO}_2\text{F}_2 / \text{g dry soil}$).

The EFSA repeated the calculations with a high OC content (20 %). The results of this calculation show that the modelled concentration in soil increases lineally with the organic carbon content ($5.09 \cdot 10^{-2} \text{ ng SO}_2\text{F}_2 / \text{g dry soil}$).

In a separated calculation, EFSA added a water compartment corresponding to 30 % of soil volume to represent the soil water content. In this more realistic soil, the concentration of sulfuryl fluoride increases more than one order of magnitude ($9.5 \cdot 10^{-2} \text{ ng SO}_2\text{F}_2 / \text{g soil}$).

The value of $9.5 \cdot 10^{-2} \text{ ng SO}_2\text{F}_2 / \text{g dry soil}$ is recommended to be used as an interim field scale PEC_s for further assessment. This value is about 7 to 8 orders of magnitude higher than the concentrations resulting from the global scale assessment. However, this value is still below that which may generally be measured with the best available analytical technology. Furthermore, it is expected that SO_2F_2 will rapidly dissipate from soil through hydrolysis and re-volatilization.

No field scale PEC_s for transformation products HSO_3F and HF are provided in addendum 3. The potential levels that may be reached by these transformation products are discussed in the EFSA addendum. No information on the fate of these transformation products in soil is available. It may be expected that HSO_3F will undergo further hydrolysis to H_2SO_4 and HF, and both HSO_3F and HF could be dissipated by leaching and drainage since they are expected to have a high mobility in soil. Even when no precise PEC_s in the vicinity of treated installations may be estimated at this stage, it may be expected that the levels of HF resulting from a realistic worst case scenario will still be below the background levels of fluoride reported in natural soils ($73 - 566 \mu\text{g F}^- / \text{Kg soil}$).³² No background levels are available for HSO_3F and further assessment may be needed to provide reassurance that the

³² Environmental Chemistry of Soils, M.B. McBride, 1994.

levels of HSO_3F that may be expected to occur in the vicinity of treated installations do not represent an environmental concern.

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

No information on the potential mobility of sulfuryl fluoride in soil is available. However, taking into consideration the low levels calculated for the soil compartment and the expected rapid hydrolysis by soil water, the potential contamination of ground water by parent sulfuryl fluoride may be precluded.

No information is available on the potential mobility of the transformation products of sulfuryl fluoride in soil. It may be expected that these highly soluble compounds will present a high mobility potential. Worst case levels of HF in soil predicted to result from the proposed uses of sulfuryl fluoride may be assumed to be significantly below background natural levels, and therefore not to contribute to the levels of fluoride in ground water. For HSO_3F no background levels are available and further assessment may be needed to provide reassurance that there is absolutely no concern with respect to potential ground water contamination.

5. Ecotoxicology

Sulfuryl fluoride was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 03) in September 2006. The risk assessment covers only the occasional use in one site (e.g. 1 x year in mills) but not frequent uses at the same site which could be the case in food storage where 1-4 fumigations are suggested per commodity depending on the duration of storage. It is not further specified how often and how frequent the product would be applied in these storage situations and no final conclusion on the exposure of non-target organisms from food commodity uses can be drawn on the basis of the data provided (the applicant has withdrawn support for these uses for Annex I evaluation).

No information was submitted on the ecotoxicological relevance of the impurity. An argumentation addressing the relevance was submitted after the experts' meeting. The applicant informed that the impurity was present in the tested technical material and hence covered by the available endpoints. Due to the high toxicity of sulfuryl fluoride it is considered unlikely that the impurity would lead to a significant increase in ecotoxicity.

5.1. Risk to terrestrial vertebrates

Sulfuryl fluoride is a gas under normal environmental conditions. The representative use is as a fumigant against insects in enclosed spaces (mills, storage facilities etc.). Sulfuryl fluoride is released to the atmosphere after treatment. Exposure of birds and mammals is possible via inhalation. The endpoints from inhalation studies with mice were compared to the concentrations of sulfuryl fluoride in the atmosphere following venting (maximum UK sulfuryl fluoride concentration of 2.46 ppm). The TER for mammals was calculated as 163, indicating a low risk. Based on the highest sulfuryl fluoride concentration of 7.02 ppm measured in the USA the resulting TER is 57. No toxicity data were made available for birds. During the peer review it was questioned whether the toxicity data for mammals can be used in the risk assessment for birds. Extrapolation of inhalation toxicity data from mammals to birds would include a high degree of uncertainty. However, the experts' meeting agreed that no toxicity studies with birds are required since significant exposure would only occur if a bird flies through the plume of gas when it is released from the building. Therefore, the experts considered the risk to birds and mammals to be low for the representative uses evaluated.

5.2. Risk to aquatic organisms

Sulfuryl fluoride is very toxic to aquatic organisms. The original TER calculations were based on global deposition of sulfuryl fluoride resulting in TERs more than 8 orders of magnitude above the Annex VI trigger of 100. However, the experts' meeting on fate and behaviour (PRAPeR 02) decided that it would be more appropriate to calculate the PEC_{sw} values for surface waters in the vicinity of

treated structures. The new PEC_{sw} values were presented in addendum 3, which was not peer reviewed. The resulting TERs were still above the Annex VI triggers of 100 and 10.

5.3. Risk to bees

No studies on toxicity to bees were submitted. However exposure of bees was considered to be negligible in view of the use as a fumigant in buildings (mills, food storage), and hence no studies with bees were required.

5.4. Risk to other arthropod species

No studies on toxicity to non-target arthropods were submitted. However exposure of non-target arthropods was considered to be negligible in view of the use as a fumigant in buildings (mills, food storage), and hence no studies with non-target arthropods were required.

5.5. Risk to earthworms

No studies on toxicity to earthworms were submitted. The original estimation of soil deposition was not accepted for the risk assessment in the experts' meeting. A new estimate for soil deposition in the vicinity of treated structures was provided in an addendum, which was not peer reviewed. The PEC_{soil} was estimated by the RMS as 5.07×10^{-6} µg a.s./g suggesting negligible exposure of soil-dwelling organisms. The EC₅₀ for earthworms would need to be $< 5.07 \times 10^{-5}$ µg a.s./g to produce a TER below the Annex VI trigger of 10. The PEC_{soil} re-calculated by the EFSA of 9.5×10^{-5} µg a.s./g (see section 4.3) was in the same order of magnitude as the value proposed by the RMS. It is not expected that such low concentrations of sulfuryl fluoride would lead to adverse effects in earthworms.

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

No data are required

5.7. Risk to soil non-target micro-organisms

No data are required. Exposure of soil micro-organisms is considered to be negligible.

5.8. Risk to other non-target-organisms (flora and fauna)

No data are required. Exposure of other non-target organisms (particularly terrestrial plants) is considered to be negligible.

5.9. Risk to biological methods of sewage treatment

No data are required. The use pattern (in enclosed spaces) and the physical-chemical properties of sulfuryl fluoride are not expected to lead to any significant entry into sewage treatment plants.

6. Residue definitions

6.1. Soil

Definition for risk assessment: SO₂F₂, HSO₃F and its salts, HF and its salts.

Definition for monitoring: predicted SO₂F₂ concentrations are below the levels feasible to measure with the current best available technology. Fluoride levels at global and field scale resulting from the use of sulfuryl fluoride are expected to be below natural background. HSO₃F and its salts are pending further assessment to completely exclude it from the monitoring residue definition.

6.2. Water

Ground water

Definition for exposure assessment: Sulfuryl fluoride, HSO_3F and its salts, HF and its salts.

Definition for monitoring: predicted sulfuryl fluoride concentrations are below the levels feasible to measure with the current best available technology. Fluoride levels at global and field scale resulting from the use of sulfuryl fluoride are expected to be below natural background. HSO_3F and its salts are pending further assessment to completely exclude it from the monitoring residue definition.

Surface water

Definition for risk assessment: Sulfuryl fluoride, HSO_3F and its salts, HF and its salts.

Definition for monitoring: predicted sulfuryl fluoride concentrations are below the levels feasible to measure with the current best available technology. Fluoride levels at global and field scale resulting from the use of sulfuryl fluoride are expected to be below natural background. HSO_3F and its salts is pending further assessment to completely exclude it from the monitoring residue definition.

6.3. Air

Definition for risk assessment: Sulfuryl fluoride

Definition for monitoring: Sulfuryl fluoride

6.4. Food of plant origin

Definition for risk assessment: Sulfuryl fluoride; Fluoride (preliminary)³³³⁴

Definition for monitoring: Sulfuryl fluoride; Fluoride (preliminary)

6.5. Food of animal origin

Definition for risk assessment: not assessed, not required for the representative uses

Definition for monitoring: not assessed, not required for the representative uses

³³ relevance of bound fluoride residues has not yet been clarified, refer to 3.1.1

³⁴ only for food uses or structure uses that lead to residues on food/feed through contamination/passive co-fumigation

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

7.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Sulfuryl fluoride	No data available, expected to have low persistence in soil through hydrolysis in soil water. Interim not peer reviewed PEC _s (global and field scale are available in EFSA addendum of July 007)	No data with soil-dwelling organisms were made available. Given the low PECs it is expected that sulfuryl fluoride would not pose a high risk to soil-dwelling organisms
HSO ₃ F and its salts	No data available, expected to undergo further hydrolysis to H ₂ SO ₄ and HF. Only lower limit PEC _s may be calculated with currently available information since the kinetic of hydrolysis of sulfuryl fluoride to HSO ₃ F and HF is not available preventing accurate calculations.	No data with soil-dwelling organisms were made available. Assuming that very low PECs are confirmed HSO ₃ F and its salts would not pose a high risk to soil-dwelling organisms
HF and its salts	No data available. Only worst case PECS may be calculated with currently available information since the kinetic of hydrolysis of sulfuryl fluoride to HSO ₃ F and HF is not available preventing accurate calculations. Available data on soil background levels of fluoride indicate that they are not likely to be affected by the proposed uses of sulfuryl fluoride.	No data with soil-dwelling organisms were made available. PECs of fluoride are expected to be below natural levels.

7.2. 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 relevance
Sulfuryl fluoride	No data available.	Potential levels in GW expected to be negligible.	Yes	Yes	Yes Very toxic to aquatic organisms

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 relevance
HSO ₃ F and its salts	No data available.	Potential levels in GW expected to be very low. In EFSA's opinion confirmation may be necessary.	No data submitted, No data required	No data submitted	No data submitted, No data required
HF and its salts	No data available.	Potential levels in GW expected to be below background levels.	No data submitted, No data required	No data submitted	No data submitted, No data required

7.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Sulfuryl fluoride Indicative global and field PEC _{sw} may be found in addendum 3 and in the EFSA addendum.	Very toxic to aquatic organisms. The risk to aquatic organisms was assessed as low based on very low concentrations in surface water.
HSO ₃ F and its salts. Indicative global and field PEC _{sw} may be found in addendum 3 and in the EFSA addendum. Further data are needed to derive field scale PEC _{sw} . Only lower limit PEC _{sw} may be calculated with	No data available. Assuming low PEC _{sw} are confirmed, HSO ₃ F and its salts would not pose a high risk to aquatic organisms.

currently available information.	
HF and its salts Indicative global and field PEC_{SW} may be found in addendum 3 and in the EFSA addendum. Further data are needed to derive field scale PEC_{SW} .	No data available. Based on the low PEC_{SW} it is expected that HSO_3F and its salts would not pose a high risk to aquatic organisms.

7.4. Air

Compound (name and/or code)	Persistence	Toxicology
Sulfuryl fluoride	Expected to be highly persistent in the troposphere. Best available information indicated that atmospheric half-life may be $DT_{50AIR} = 10$ yr or higher. Indicative global scale PEC_{AIR} are available in the EFSA addendum and indicative field scale PEC_{AIR} may be found in addendum 3 of May 2007.	Toxic by Inhalation Harmful: danger of serious damage to health by prolonged exposure through inhalation

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

- Applicant to provide additional information (the McDonald and Hildenbrand 1957 Study, Some physical properties of sulfuryl fluoride) concerning the vapour pressure (relevant for all representative uses evaluated; submission date: submitted, but not peer-reviewed; refer to chapters 1 and 4).
- Applicant to provide a monitoring method for the determination of sulfuryl fluoride residues in air with an LOQ below or equal to 4.2 mg/m³ (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; refer to chapters 1 and 2).
- Applicant to provide preferably the study with radio-labelled sulfuryl-S³⁵-fluoride in wheat flour, or if not available, at least a copy of the publication (relevant for all representative uses evaluated except the use in an empty grain store; data gap identified at PRAPeR 05; applicant has submitted a copy of the publication in February 2007, EFSA considers that the submission does not address the data gap, however this has not been peer reviewed).
- Applicant to provide clarification of whether protein-bound fluoride is bio-available under physiological conditions, and to address the fate of fluorinated amino acids in the organism, and the potential for accumulation of fluorocarbons in body tissue (relevant for all representative uses evaluated except the use in an empty grain store; data gap identified at PRAPeR 05; applicant has submitted a position paper in February 2007, but whether the submission addresses the data gap has not been peer reviewed).
- Applicant to provide a residue study in tree nuts to simulate the fumigation of large bags/containers/stacks with greater propensity for dead spaces and therefore potential higher residue levels of sulfuryl fluoride and fluoride (relevant for the representative use in tree nuts, which has since been withdrawn; data requirement identified in the DAR; applicant submitted a study with tree nuts in 2006, but the data were not evaluated by the RMS and have therefore not been peer reviewed).
- To the support the uses in dried fruits, applicant to provide a residue study in tree nuts to simulate the fumigation of large bags/containers/stacks with greater propensity for dead spaces and therefore potential higher residue levels of sulfuryl fluoride and fluoride (as noted above). The knowledge from the nut study will then be used to extrapolate to the use in dried fruit. (Relevant for the representative use in dried fruit, which has since been withdrawn; data requirement identified in the DAR, however PRAPeR 05 has concluded that no such extrapolation is possible; applicant has submitted a study with dried fruit in 2006, but the data was not evaluated by the RMS and has therefore not been peer reviewed).
- Applicant to provide methods of analysis for determining fluoride residue in dried fruit and tree nuts with a lower LOQ (relevant for the representative uses in tree nuts and dried fruit, which have since been withdrawn; data requirement identified in the evaluation table; applicant has submitted a validated method with an LOQ of 0.5 mg/kg in 2006, but the data were not evaluated by the RMS and have therefore not been peer reviewed).
- Applicant to provide information on the natural levels of fluoride ion in wheat flour, such that Member States would be able to assess what LOQ would be necessary in order to be confident that following any treatment of an empty flour mill with sulfuryl fluoride any management measure implemented (eg. disposal of subsequent initial production) could be confirmed as preventing any potential increase in the fluoride dietary burden above usual background levels (relevant for the representative use in an empty flour mill; no submission date proposed by the applicant).

- A monitoring programme of tropospheric concentrations of sulfur dioxide should be put in place. The LOQ for the analysis should be below or equal to 0.5 ppt. Measured concentration should be updated regularly (relevant for all representative uses).
- To enable the actual volume of usage to be taken into account in confirming or refining the predictions of the atmospheric lifetime of sulfur dioxide, sales figures should be provided for agricultural and non-agricultural uses both in Europe and globally (relevant for all representative uses).
- Data gap identified for a reliable atmospheric lifetime (Data gap identified in evaluation table 4.11; relevant for all representative uses evaluated; a new assessment was presented by the applicant in January in 2007 and summarized in addendum 3 but did not take into account information available at the time to the scientific community, a new assessment was provided by the EFSA in an addendum of July 2007; neither addendum 3 nor the EFSA addendum are peer reviewed; more recent estimations are available in the scientific literature;¹⁸ refer to chapter 4).
- Data gap identified for Level II fugacity model results calculated according to the scenario approach agreed by the PRAPeR 02 meeting (atmospheric lifetime of 4.5, 15, 50 and 100 yr and production rates of years (1992 – 2000) and 2, 5 and 10 times as much; these calculations should provide global scale PEC_{AIR} and $PECs$ for the parent compound. (Data gap identified in evaluation table 4.13; relevant for all representative uses evaluated; new Level II calculations were provided in January 2007 and were summarized by the RMS in addendum 3, the addendum is not peer reviewed but the EFSA assessment notes that the indications of the PRAPeR meeting have been overlooked, new Level II calculation were performed by the EFSA and provided in the EFSA addendum; neither addendum 3 nor the EFSA addendum are peer reviewed; refer to chapter 4).
- Data gap identified for an updated calculation of GWP (global warming potential), to be re-calculated according to the scenario approach proposed by the PRAPeR 02 meeting, or at least according to the best atmospheric half-life now available (Data gap in evaluation table 4.12; relevant for all representative uses; no submission date proposed by the applicant; new data available in the scientific literature; refer to chapter 4).
- Data gap identified for a field scale aquatic risk assessment (data gap in evaluation table 4.10; relevant for all representative uses; applicant provided PEC_{SW} calculations in January 2007, the PEC_{SW} at field scale for the parent compound was re-calculated by the RMS in addendum 3, this value has not been peer reviewed but the EFSA considers this value to represent a reasonable worst case; however, additional data are needed to address field scale PEC_{SW} for hydrolysis transformation products and assessment of potential surface water acidification; refer to chapter 4).
- Data gap identified for a field scale soil assessment (data gap in evaluation table 4.7 and 4.8; relevant for all representative uses; applicant provided PEC_s calculations for parent compound in January 2007 and these are summarised in addendum 3. EFSA has re-calculated Level I PEC_s calculations taking into consideration partition to soil moisture, obtaining a more worst case PEC_s ; neither addendum 3 nor the EFSA addendum are peer reviewed; refer to chapter 4).
- Data gap identified for further assessment of wet deposition and potential contamination of soil and continental waters by transformation products (data gaps in evaluation table 4.7 and 4.9) (relevant for all representative uses evaluated; information has been provided by the applicant in January 2007 and summarized in addendum 3 by the RMS; EFSA re-calculated the values in accordance with the best current available atmospheric half-life and presented these in the EFSA addendum; additional data may be needed to address field scale PEC_s for hydrolysis transformation products and assessment of potential soil acidification; neither addendum 3 nor the EFSA addendum are peer reviewed; refer to chapter 4).

- Applicant to submit information on the ecotoxicological relevance of the impurity (data gap identified in PRAPeR 03; relevant for all representative uses; argumentation to address the ecotoxicological relevance was submitted and included in an addendum from May 2007, which has not been peer reviewed; refer to chapter 5).

CONCLUSIONS AND RECOMMENDATIONS

OVERALL CONCLUSIONS

The conclusion was reached on the basis of the evaluation of the representative uses as an insecticide, comprising application as a fumigant in food storage to control all life stages of arthropods (e.g. meal moths, flour and grain beetles) in emptied flour mills and empty grain storage facilities at maximum concentrations of 128 g/m³ (CTP = 1500 (Concentration X Time Product)). Details of the applications and timings can be found in the attached list of end points. The uses submitted in the DAR on dried fruit and tree nut commodities were withdrawn by the applicant for the EU evaluation.

The representative formulated product for the evaluation was 'ProFume', a gas (GA), registered under different trade names in Europe. The formulation contains 99.4 % w/w sulfuryl fluoride pure (the technical active substance is the product).

Several methods are available to monitor the compounds given in the respective residue definitions for food of plant origin, in blood and urine, however additional data may be required after the finalization of the residue definitions in the different matrices. A data gap was identified for a method for the determination of sulfuryl fluoride in air.

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 product are possible.

Sulfuryl fluoride is toxic by inhalation and is classified as Harmful; R48/20 'Danger of serious damage to health by prolonged exposure/inhalation route'. It is proposed for classification as T; R25 ('Toxic if swallowed') and Xi; R37 ('Irritating to the respiratory system'). The relevant short-term exposure No Observed Adverse Effect Levels (NOAELs) are 30 ppm in mice and rabbits, 20 ppm in dogs and 100 ppm in rats. The long-term NOAEL is 20 ppm. Sulfuryl fluoride does not show any genotoxic or carcinogenic potential. It is not a reproductive or developmental toxicant. The Acceptable Daily Intake (ADI) is 0.014 mg/kg bw/day, the Acute Reference Dose (ARfD) is 0.7 mg/kg bw and the Acceptable Operator Exposure Concentration (AOEC) is 1 ppm. For the bystander exposure assessment, an AOEC of 3 ppm was set. The RMS concluded that operators introducing fumigant or carrying out tasks associated with the aeration procedure should wear suitable respiratory protective equipment. Based on the available data, a 10 metre exclusion zone around the fumigated structure is considered to protect unprotected persons (i.e. bystanders) from levels of sulfuryl fluoride above 3 ppm.

Metabolism studies that address the nature of the residues on food commodities upon fumigation with sulfuryl fluoride were not submitted. Therefore it was discussed by experts whether the metabolism or mode of degradation, respectively, of sulfuryl fluoride in food and feed commodities was sufficiently addressed and whether there was satisfactory proof from the information and papers submitted, that the proposed breakdown mechanism is identical in all matrices as suggested by the applicant. The experts concluded that the available information is not sufficient to assess the involved reactions, to verify the reported results or to confirm that sulfuryl fluoride and free fluoride ion will be the only relevant residues the consumer may be exposed to. Therefore the consumer risk assessment, mainly with regard to the nature of the residue, cannot be finalised.

Even though uses on the fumigation of food items (dried fruits, nuts) were withdrawn during the peer review procedure and only uses for structural treatments remain, there is still the potential for consumer exposure to inorganic fluoride through contaminated products, such as flour and bran that

remained in the mill machinery during fumigation, or grain stored in silos in the mill. Available data show that high fluoride residue levels in flour and bran occurred after the production in a treated mill structure had been taken up again. Therefore, if in practice contamination per se cannot be avoided, then measures to avoid contaminated cereal products entering the food chain are necessary.

The RMS suggested that separate MRLs for the fluoride ion should be proposed based on background levels. However, there are currently no agreed acceptable fluoride background levels in food products in the EU and therefore the allocation of an adequate MRL for fluoride might be difficult. Any higher MRL than at natural background levels would trigger a consumer exposure risk assessment. It is noted that such an assessment would also need to consider other sources of fluoride exposure.

Sulfuryl fluoride is a gas under all environmental conditions (boiling point -54 °C). The vapour pressure is deemed to be high according to the available data. Potential degradation routes for sulfuryl fluoride were analysed in the DAR. All routes were considered negligible except the chemical hydrolysis that may occur in ocean waters.

The initial assessment of the fate and behaviour of sulfuryl fluoride in the environment was based on a limited set of experimental data (essentially limited to the physical and chemical properties of the substance) and a number of assumptions and indirect information (such as production figures and atmospheric half-life) that were used as input parameters in the fugacity models employed for the assessment of the fate and behaviour of the substance at global scale. Assessment of the fate and behaviour of sulfuryl fluoride at the field scale level was not presented by the applicant in the initial submission. Also the fate and behaviour of hydrolysis transformation products was not addressed. A number of data gaps were identified in the early stages of the peer review to properly document the information used in the assessment.

One of the key parameters used in the assessment is the atmospheric lifetime. The value used by the applicant was derived from a presumed monitored tropospheric concentration only available by a personal communication of one of the scientists involved. The experts' meeting considered that the data provided were not documented enough for regulatory purposes and identified a data gap for the determination of atmospheric lifetime.

At the experts' meetings (PRAPeR 02 and 03) on environmental fate and behaviour and ecotoxicology, respectively, the RMS was asked to undertake further assessment: in particular on wet deposition and the potential for contamination of soil and water by transformation products of sulfuryl fluoride; to evaluate field-scale PEC values in soil and surface water close to treated installations and revised fugacity modelling to calculate global-scale PECs in soil, water and air. Additional estimates were also requested of global warming potential (GWP), based on worst case atmospheric lifetime and anticipated sales volumes. These points have been largely addressed by the RMS in the addendum of May 2007 based on the information provided by the applicant. However, the new assessment provided by the applicant and presented by the RMS in the addendum did not strictly follow the scenario approach proposed by the experts' meeting (only lifetime of 4.5 yr was used and production figures were generally limited to historical records from 1992-2000), and does not take into consideration the most recent information available at the time. This information is crucial since it supersedes the information used by the applicant to estimate the atmospheric lifetime of the substance on which most of the fate and behaviour assessment of sulfuryl fluoride is based. As a consequence, the EFSA re-calculated parts of modelling presented by the applicant and the RMS in the addendum 3 of May 2007. The most relevant results are presented in this conclusion, and the background input parameters and calculations are documented in the EFSA addendum of July 2007.

With respect to the field scale assessment, EFSA did a preliminary sensitivity analysis of the assumptions used in the field scale soil assessment (based on LEVEL I fugacity model) and added some considerations to address the transformation products of sulfuryl fluoride at field scale.

Neither the RMS addendum nor the EFSA addendum has been peer reviewed. In the following table the PEC calculated by EFSA at global and field scale for the different environmental compartments are presented.

	PEC _{AIR}		PEC _{SW}		PEC _S	
	Global scale ppt (ng / m ³)	Field scale ppm (mg/m ³)	Global scale (ng / L)	Field scale (µg / L)	Global scale (ng / Kg)	Field scale (µg / Kg)
SO ₂ F ₂	1 – 10 (4.7 – 47.2)	7.02 (29)	7.3·10 ⁻⁵ - 7.3·10 ⁻⁴	0.459 ⁺	8.3·10 ⁻¹⁰ - 8.3·10 ⁻⁹	9.5·10 ⁻²
HSO ₃ F	n.c.	n.c.	0.73 – 7.30 [#]	>0.45	9.1·10 ⁻⁴ - 9.1·10 ⁻³	>9.3·10 ⁻²
HF	n.c.	n.c.	0.14 – 1.40* [#]	>0.09 [*]	1.8·10 ⁻⁴ - 1.8·10 ⁻³ **	>1.86·10 ⁻² **

n.c. not calculated. transformation products are expected to be dissociated and not volatilize.

⁺ Calculated by RMS in addendum 3.

* Natural background surface water concentrations of F⁻ are in the range of 10 – 300 µg / L

** Natural background soil concentrations of F⁻ are in the range of 73 – 566 µg / Kg

[#] Higher values based on a 10-fold increase in emissions over 10 yr.

A number of data gaps were identified during the peer review. The main areas of concern from the fate and behaviour point of view are the high uncertainty associated with the atmospheric lifetime (the best available estimate at the time EFSA prepared the addendum was about 15 yr) and the intrinsic global warming potential that needs to be re-calculated. At the time of finalising this conclusion (December 2009), values previously estimated based on measurements of the AGAGE network have been refined and a longer atmospheric lifetime than previously reported is recently quoted in the scientific literature (36 ± 11 yr). Based on these recent data, a GWP of 4780 for the 100 years horizon has been published.

Sulfuryl fluoride is very toxic to aquatic organisms. However due to the specific use and the physical-chemical properties of the substance exposure of non-target organisms is considered to be negligible, and hence the risk to non-target organisms is considered to be low.

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

- Use of PPE for operators and workers (SCBA).
- A 10 metre exclusion zone around the fumigated structure is required to protect unprotected persons (i.e. bystanders).
- Measures are required to ensure that contaminated flour (above natural background levels) from mill fumigation uses does not enter the food chain (refer to 3.1.1 and 3.4). Disposal of the pre-production and first hour (or more if required) of production, or dilution by re-processing was proposed by the RMS and the applicant, respectively.

ISSUES THAT COULD NOT BE FINALIZED

- The consumer risk assessment cannot be finalised for the uses where sulfuryl fluoride comes into contact with food and no MRL proposals for sulfuryl fluoride and fluoride ion were agreed.
- The fate and behaviour risk assessment cannot be finalised. There are uncertainties in the atmospheric lifetime due to the uncertainty in the available monitoring information. Experts considered that future monitoring of tropospheric concentration should be undertaken if sulfuryl

fluoride is listed in Annex I of Directive 91/414/EEC. Such an approach would be in line with the specific provisions listed in the inclusion of sulfuryl fluoride in Annex I of Directive 98/8/EC (Commission Directives 2006/140/EC and 2009/84/EC refer) in the framework of the biocide programme. In addition, to enable the actual volume of usage to be taken into account in confirming or refining the predictions of the atmospheric lifetime of sulfuryl fluoride, authorisation holders should be required to submit sales figures for agricultural and non-agricultural uses both in Europe and globally.

CRITICAL AREAS OF CONCERN

- The substance has intrinsic global warming potential. Actual GWP_{100} needs to be re-calculated based on the atmospheric lifetime derived from the most recent monitoring measurements. Recent estimations available in the scientific public literature indicate a GWP_{100} of 4780.³⁵ This value is within the range of the values calculated for other chemicals regulated under the Kyoto protocol agreement (eg HFC-134a: $GWP_{100} = 1430$; sulphur hexafluoride: $GWP_{100} = 22800$). Potential contributions of sulfuryl fluoride to the global greenhouse effect will need to be assessed with respect to actual and potential overall amount used as a result of its different applications (pesticide, biocide, insulating gas).
- Estimates of atmospheric lifetime have a high degree of uncertainty (this is the reason for the proposed data requirement on monitoring and sales). The best available estimation of tropospheric lifetime at the time of this assessment was about 15 yr. More recent estimations available in the scientific public literature indicate a lifetime of 36 ± 11 yr.

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³⁵ GWP is expressed relatively to CO₂ (i.e. $GWP_{100}(\text{CO}_2) = 1$).

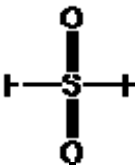
APPENDICES

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

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

Active substance (ISO Common Name) ‡	Sulfuryl fluoride (no ISO common name)
Function (<i>e.g.</i> fungicide)	Insecticide (Fumigant)
Rapporteur Member State	UK

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Sulfuryl fluoride
Chemical name (CA) ‡	Sulfuryl fluoride
CIPAC No ‡	757
CAS No ‡	002699-79-8
EEC No (EINECS or ELINCS) ‡	220-281-5
FAO Specification (including year of publication)‡	Not available
Minimum purity of the active substance as manufactured (g/kg) ‡	≥994 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Open
Molecular formula ‡	F ₂ O ₂ S (SO ₂ F ₂)
Molecular mass ‡	102.1 g/mol
Structural formula ‡	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Estimated to be -137°C
Boiling point (state purity) ‡	-54°C
Temperature of decomposition	Not determined as it is a gas at room temperature
Appearance (state purity) ‡	Colourless gas
Vapour pressure (in Pa, state temperature) ‡	1.6×10^6 Pa at 20°C (calculated)
Henry's law constant ($\text{Pa m}^3 \text{mol}^{-1}$) ‡	1.6×10^5 $\text{Pa m}^3 / \text{mol}$ at 20°C (calculated)
Solubility in water (g/l or mg/l, state temperature) ‡	1.04 g/l unbuffered at 20°C Range of pH's were not looked at as sulfuryl fluoride does not dissociate
Solubility in organic solvents (in g/l or mg/l, state temperature) ‡	n-heptane 22g/l at 20°C methanol 33g/l at 20°C acetone 71g/l at 20°C xylene 25g/l at 20°C 1,2-dichloromethane 25g/l at 20°C ethyl acetate 59g/l at 20°C
Surface tension	68 mN/m (90% saturated aqueous solution)
Partition co-efficient ($\log P_{ow}$) (state pH and temperature) ‡	$\log P_{ow} = 0.14$ at 20°C Range of pH's were not looked at as sulfuryl fluoride does not dissociate in water
Dissociation constant ‡	Sulfuryl fluoride has no acidic or basic properties in aqueous solutions. It is therefore impossible to specify dissociation constants of the active ingredient in water
UV/VIS absorption (max.) (if absorption > 290 nm state ϵ at wavelength) ‡	UV absorb 276 nm ($\epsilon = 37 \text{ l mol}^{-1} \text{ cm}^{-1}$). 290 nm ($\epsilon = 25 \text{ l mol}^{-1} \text{ cm}^{-1}$) No UV absorbance above 290 nm.
Flammability ‡	The chemical structure and the absence of carbon in sulfuryl fluoride supports the case for sulfuryl fluoride being classified as non-flammable
Explosive properties ‡	Not applicable as test substance is a gas
Oxidizing properties	Not oxidising

Summary of representative uses evaluated (sulfuryl fluoride)*

Crop and/or situation	Member State or Country	Product Name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
					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 (l) min max	water (L/ha) min max	kg a.s./ha min max	(m)	
Stored product pests in emptied cereal mills, empty grain storage areas (A1)	UK (GB) France (FR) Germany (DE) Italy (IT)	ProFume	I (Fumigant)	Stored product insect pests: <i>Ephestia kuehniella</i> (EPHEKU) <i>Plodia interpunctella</i> (PLODIN) <i>Tribolium</i>	Fumigant Gas. Packaged as a liquid under pressure. As liquid is released it immediately	99.8%	Fumigation of building or storage container by releasing fumigant from cylinder, confining for 2-72+ hrs and then	Post Harvest	1/year	N/A A particular plant will be fumigated on a schedule which ranges from 3	Units are different for a fumigation product. CTP= Concentration X Time Product. Max. CTP	N/A Fumigant will be used as gas.	N/A Units are not applicable for a fumigant	N/A. All treatments are post harvest.	The dosage (concentration x exposure time) used is dependent on the temperature, species

* Uses for which the risk assessment can not be concluded are marked grey.

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance sulfuryl fluoride. EFSA Journal 2010; 8(1):1441. [66 pp.]. doi:10.2903/j.efsa.2010.1441. Available online: www.efsa.europa.eu

Crop and/or situation	Member State or Country	Product Name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
					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 (l) min max	water (L/ha) min max	kg a.s./ha min max		
(a)			(b)	(c)										(m)	
				<i>castaneum</i> (TRBCA) <i>Tribolium confusum</i> (TRBCO) <i>Trogoderma variabile</i> (TROBPA) <i>Oryzaephilus surinamensis</i> (ORYZSU)	converts to a gas state and disperses in the confined space of the fumigation.		aerating fumigant until ambient air concentration is ≤ 3 ppm.			times per year to once every few years.	= 1500. Max Conc. is 128 g/m ³				and life stage. Representative fumigation conducted with a 24 h fumigation at about 25°C

Crop and/or situation	Member State or Country	Product Name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
					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 (l) min max	water (L/ha) min max	kg a.s./ha min max		
Postharvest Commodities Dried Fruits (e.g. raisins, prunes, apricots, etc.) and Tree Nuts (e.g. walnuts, almonds, pistachios). Fumigation	UK (GB) France (FR) Germany (DE) Italy (IT)	ProFume	I (Fumigant)	Stored Product Insect Pests. Examples include beetles eg <i>Oryzaephilus surinamensis</i> (ORYZSU), <i>Trogoderma variabile</i> (TROBPA) and others, as well as Lepidoptera (KLV) pests such as <i>Ephestia kuehniella</i> (EPHEKU), <i>Plodia</i>	Fumigant Gas. Packaged as a liquid under pressure. As liquid is released it immediately converts to a gas state and disperses in the confined space of the fumigation.	99.8%	Fumigation. Release fumigant from cylinder into confined air space, confine gas for 2–72+ hours, then exhaust. Vacuum fumigation follows same procedure, with vacuum to increase insecticidal activity.	Post-harvest pest control	1–4 x per commodity Most commonly only fumigated 1-2 times. Depends on length of commodity storage	Generally several months, if refumigation occurs at all. Refumigate when commodity becomes reinfested during storage.	Short term fumigation of 2 to 4 h exposure using max 128 g/m ³ (CTP 1500). Standard exposure of 24 to 48 h. Dosage decreases as temperature increases.	N/A Fumigant is released as a liquid gas under pressure	N/A	N/A All treatments are post harvest. Consumption is allowed after parent (sulfuryl fluoride) has dissipated	The dosage (concentration x exposure time) used is dependent on the temperature. Max Concentration x Time dosage range for stored product insects expected to be 1500

Crop and/or situation	Member State or Country	Product Name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
					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 (l) min max	water (L/ha) min max	kg a.s./ha min max		
of stored commodity in permanent or temporary chambers				<i>interpunctella (PLODIN)</i>											g-h/m ³ . Representative fumigation conducted with a 24 h fumigation at about 25°C.

Post harvest uses no longer supported by the applicant for the EU process

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse 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
- (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
- (m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical as (principle of method)	Sulfuryl fluoride was determined in the technical active substance by GC-TCD
Impurities in technical as (principle of method)	Impurities in technical active substance were determined by GC-TCD.
Plant protection product (principle of method)	Sulfuryl fluoride was determined in the plant protection products by GC-TCD.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Sulfuryl fluoride residues in a number of commodities were determined by blending them in an airtight blender, in water and the resulting head space analysed by GC-ECD. The limit of determination was 0.004 – 0.01 mg/kg. Fluoride residues in a number of commodities were determined by extraction with de-ionised water/Ionic Buffer and the resulting extract analysed using a fluoride ion specific electrode. The limit of determination was 0.5 – 5.0 mg/kg.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No method was submitted or required, due to no uses being proposed on animal feed products.
Soil (principle of method and LOQ)	No methods were submitted or required, due to only the interior of buildings being treated.
Water (principle of method and LOQ)	No methods were submitted or required, due to only the interior of buildings being treated.
Air (principle of method and LOQ)	Open
Body fluids and tissues (principle of method and LOQ)	The fluoride ion-selective electrode method for fluoride is essentially universal in all matrices tested, including plasma, urine and tissues, not specific to sulfuryl fluoride.

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	None
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Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

No data submitted on route of degradation of sulfuryl fluoride in soil. As a permanent gas for use as a fumigant, exposure to soil is expected to be minimal. Biological degradation expected to be negligible. However, sulfuryl fluoride partitioned in soil is expected to re-volatilize and to undergo hydrolysis with the soil moisture. Data gap for further assessment identified by PRAPeR 02.

Mineralization after 100 days ‡	No data available, no data required
Non-extractable residues after 100 days ‡	N/A - as above.
Relevant metabolites - name and/or code, % of applied (range and maximum) ‡	Potential hydrolysis transformation products that may occur in soil are HSO_3F and HF . Further assessment required by PRAPeR 02. Non peer reviewed assessments provided in addendum 3, EFSA addendum and EFSA conclusion. HF levels expected to be below natural fluoride. Further assessment may be needed for HSO_3F . This assessment would need to be updated once half life in the atmosphere and release estimates are confirmed.

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

Anaerobic degradation ‡	No data available, no data required.
Soil photolysis ‡	No data available, assumed to be negligible.

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

Method of calculation	N/A - No data submitted on rate of degradation of sulfuryl fluoride in soil. As a permanent gas for use as a fumigant, exposure to soil is expected to be minimal. Hydrolysis assumed to be the main degradation process in soil.
Laboratory studies (range or median, with n value, with r^2 value) ‡	<p>$\text{DT}_{50\text{lab}}$ (20°C, aerobic): No data available, see above.</p> <p>$\text{DT}_{90\text{lab}}$ (20°C, aerobic): No data available, see above.</p> <p>$\text{DT}_{50\text{lab}}$ (10°C, aerobic): No data available, see above.</p> <p>$\text{DT}_{50\text{lab}}$ (20°C, anaerobic): No data available, see above.</p> <p>degradation in the saturated zone: No data available, no data required.</p>
Field studies (state location, range or median with n value) ‡	$\text{DT}_{50\text{f}}$: no data available, dissipation of SO_2F_2 in soil assumed to be rapid by revolatilization and hydrolysis. Field studies not expected to be triggered.

Soil accumulation and plateau concentration ‡

DT_{90f}: see above.

N/A – see above. Accumulation of hydrolysis transformation products may need further assessment. Non peer reviewed assessments provided in addendum 3, EFSA addendum and EFSA conclusion.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡

K_d ‡

pH dependence (yes / no) (if yes type of dependence) ‡

No data submitted on adsorption or desorption of sulfuryl fluoride in soil. As a permanent gas for use as a fumigant, exposure to soil is expected to be minimal. Contamination of ground water by parent sulfuryl fluoride may be precluded on basis of the expected rapid dissipation from soil. Sulfuryl fluoride transformation products expected to be highly mobile in soil. According EFSA non-peer reviewed assessment levels of HF in soil produced by SO₂F₂ are expected to be considerably lower than background soil fluoride levels. Further assessment may be needed for H₂SO₃F and its salts, since no background levels are known.

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡

No data available, no data required.

Aged residues leaching ‡

No data available, no data required.

Lysimeter/ field leaching studies ‡

No data available, no data required.

Revised PEC_{soil}

Method of calculation

EQC (Equilibrium Criterion) Fugacity Model - Level II (Global-scale only), excluding double counting of degradation in ocean water. Data gap for a reliable atmospheric half-life identified by PRAPeR 02 to allow global PEC calculations. Indicative non-peer reviewed value based on most recent monitoring data may be found in EFSA addendum.

Application rate

Based on a mass input of 1.82×10^6 kg/year, (an average annual emission from existing emissions 1992-2000 data). This does not take into account future higher emissions including the proposed plant protection product uses. Required to be confidential by the applicant.

PEC_(soil)

Data gap identified by PRAPeR 02 meeting. Indicative non-peer reviewed values may be found in EFSA addendum.

Potential for wet deposition of parent to soil:

Method of calculation

Assuming:
DT50 hydrolysis of 10.4 d (at pH 5.6 and 15°C),
HLC of 158142 Pa m³ mol⁻¹ giving washout ratio of 0.015, precipitation of 100 cm/y.
 $J = C_{air} \times W_r \times I$
(where J = flux to soil, C_{air} = concentration in air, W_r = washout ratio, I = rainfall rate)

Potential for wet deposition to soil

Calculation cannot be performed without a reliable atmospheric half-life. Data gap identified by PRAPeR 02 meeting. Indicative values may be found in EFSA addendum.

Field-scale PEC_{soil}:

Method of calculation

Level 1 Fugacity Model. 100 m radius, 1km atmospheric elevation (actually result is independent of this parameter), surface area 31,400 m², air compartment 31400,000 m³. Soil depth 5cm. Assuming maximum uni-directional 24 h TWA concentration for residential bystander exposure of 7.02 ppm at 5m and total mass of sulfuryl fluoride of 910.6 kg.

Field-scale PEC_{soil}

Data gap identified by PRAPeR 02 meeting. Indicative non-peer reviewed values may be found in addendum 3 and EFSA addendum and EFSA conclusion.

Metabolite

Potential for wet deposition of metabolites to soil:

Method of calculation

Data gap identified by PRAPeR 02 meeting. Indicative non-peer reviewed value based on most recent monitoring data may be found in EFSA addendum and EFSA conclusion.

Potential for wet deposition to soil

Data gap identified by PRAPeR 02 meeting. Indicative non-peer reviewed value based on most recent monitoring data may be found in EFSA addendum and EFSA conclusion.

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

Hydrolysis of active substance and relevant metabolites (DT₅₀) (state pH and temperature) ‡

At pH 7 and 20°C _____: 6.7 hours
At pH 9 and 20°C _____: 4 minutes

At pH 2 and 25°C _____: 128 hours*
At pH 5.9 and 25°C _____: 74 hours*
At pH 5.6 and 15°C _____: 10.4 days
*Hydrolysis rates under acidic conditions are only approximate values.

Photolytic degradation of active substance and relevant metabolites ‡

Photolytic degradation expected to be negligible in the troposphere based on S-F bond energy.

Readily biodegradable (yes/no) ‡

Not applicable for inorganic compounds.

Degradation in - DT₅₀ water ‡
water/sediment - DT₉₀ water ‡
- DT₅₀ whole system ‡
- DT₉₀ whole system ‡

No study submitted, not required.

Mineralization

No study submitted, not required.

Non-extractable residues

No study submitted, not required.

Distribution in water / sediment systems (active substance) ‡

No study submitted, not required.

Distribution in water / sediment systems (metabolites) ‡

No study submitted, not required.

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

Parent

Revised PEC_{sw}

Method of calculation

EQC (Equilibrium Criterion) Fugacity Model - Level II (Global-scale only), excluding double counting of degradation in ocean water. Data gap for a reliable atmospheric half-life identified by PRAPeR 02 to allow global PEC calculations. Indicative non peer reviewed value based on most recent monitoring data may be found in EFSA addendum and EFSA conclusion.

Application rate

PEC_{sw} based on a mass input of 1.82×10^6 kg/year, (an average annual emission from existing emissions 1992-2000 data). This does not take into account future higher emissions including the proposed plant protection product uses. Required to be confidential by the applicant.

Main routes of entry

Partitioning from the atmosphere. Sulfuryl fluoride is expected to be uniformly distributed in the atmosphere, globally. Therefore, 97-99% of surface water potentially exposed is assumed to be ocean water.

PEC_(sw)

Data gap identified by PRAPeR 02. Indicative non peer reviewed values may be found in EFSA addendum and EFSA conclusion.

Potential for wet deposition of parent to continental waters:

Method of calculation

Assuming:
DT50 hydrolysis of 10.4 d (at pH 5.6 and 15°C),
HLC of $158142 \text{ Pa m}^3 \text{ mol}^{-1}$ giving washout ratio of 0.015, precipitation of 100 cm/y

$J = C_{\text{air}} \times W_r \times I$
(where J = flux to soil, C_{air} = concentration in air, W_r = washout ratio, I = rainfall rate)

Potential for wet deposition of parent to water

Calculation cannot be performed without a reliable atmospheric half-life. Data gap identified by PRAPeR 02 meeting. Indicative non peer reviewed values may be found in EFSA addendum and EFSA conclusion.

Field-scale PEC_{sw}:

Method of calculation

$C_{\text{sw}} = C_{\text{air}} / H$ where

$C_{\text{air}} = \max 24 \text{ h TWA multi-directional concentration from residential bystander exposure of } 7.02 \text{ ppm and } H = 158142 \text{ Pa m}^3 \text{ mol}^{-1}$

Field-scale PEC_{sw}

Data gap identified by PRAPeR 02 meeting. Indicative non peer reviewed value that may be found in addendum 3 and EFSA conclusion.

Metabolite

Potential for wet deposition of metabolites to continental waters:

Method of calculation

Data gap identified by PRAPeR 02 meeting. Indicative non peer reviewed values based on most recent monitoring data may be found in EFSA addendum and EFSA conclusion.

Potential for wet deposition of metabolites to surface water

Data gap identified by PRAPeR 02 meeting. Indicative non peer reviewed values based on most recent monitoring data may be found in EFSA addendum and EFSA conclusion.

PEC (sediment)

Parent

Revised PEC_{sed}

Given the low amounts predicted to partition to water and rapid hydrolysis in ocean water, exposure to sediment is expected to be negligible.

Method of calculation

Application rate

Mass input of 1.82×10^6 kg/year assumed (1992-2000 data). Required to be confidential by the applicant.

PEC_(sed)

Indicative non peer reviewed value may be found in addendum 3 based on an atmospheric half-life that has been superseded by more recent monitoring data; this value was multiplied by 1000-fold to obtain a worst case that was proposed by the RMS as sufficiently conservative for use in ecotoxicological assessment.

Metabolite

Method of calculation

No data available, no data required.

Application rate

No data available, no data required.

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)

Not considered to have any potential to contaminate ground water above the maximum acceptable concentration of 0.1 µg/l, on the basis of the very low residues expected to be present in soil following proposed use. Trigger of 0.1 µg/L not applicable to inorganic compounds.

Application rate

N/A

PEC (ground water) Metabolite

Method of calculation

According EFSA non-peer reviewed assessment levels of HF in soil produced by SO_2F_2 are expected to be considerably lower than background soil fluoride levels. Further assessment may be needed for $\text{H}_2\text{SO}_3\text{F}$, since no background levels are known.

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

Direct photolysis in air ‡	Minimum atmospheric photodissociation half-life for sulfuryl fluoride estimated as 2.9 and 1.6 years at 0 and 10 km altitude, respectively.
Quantum yield of direct phototransformation	Assumed as 1.
Photochemical oxidative degradation in air ‡	See above (direct photolysis).
Volatilization ‡	from plant surfaces: No data submitted. Gas under environmental conditions.
	from soil: No data submitted. Gas under environmental conditions.

PEC (air)

Method of calculation	Data gap identified by PRAPeR 02 meeting. Indicative non peer reviewed values based on most recent monitoring data may be found in EFSA addendum and EFSA conclusion.
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Revised PECair

Maximum concentration	Data gap identified by PRAPeR 02 meeting. Indicative non peer reviewed values based on most recent monitoring data may be found in EFSA addendum and EFSA conclusion. Indicative non peer reviewed, field scale air concentrations based on workers and bystanders exposure monitoring studies available in RMS addendum.
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Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Sulfuryl fluoride in air
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Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	New use, therefore monitoring data not yet available.
Surface water (indicate location and type of study)	New use, therefore monitoring data not yet available.
Ground water (indicate location and type of study)	New use, therefore monitoring data not yet available.
Air (indicate location and type of study)	New use, therefore monitoring data showing the effect of the new uses not yet available. Active

substance used already for many years as biocide. Monitoring data provided in the dossier (as authors personal e-mail communication) was found not to be sufficiently documented for regulatory purposes by PRAPER 02 meeting. New monitoring data are available in the form of an abstract of a presentation to a scientific meeting. These data has been used by EFSA in the non-peer reviewed assessment presented in the EFSA addendum and the EFSA conclusion. Some data have been updated by more recent observations and published in scientific peer reviewed journals.

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data

None

Effects on Non-target Species

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

Acute toxicity to mammals ‡	LC50 (inhalation): 400 ppm/1.67 mg/l (mouse) ¹
Acute toxicity to birds ‡	No data available ¹
Dietary toxicity to birds ‡	No data available ¹
Reproductive toxicity to birds ‡	No data available ¹

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

Application rate (g as/m ³)	Crop ²	Category (e.g. insectivorous bird)	Time-scale	TER ¹	Annex VI Trigger
128	Fumigation chamber	Small mammal	Acute	163	-
128	Fumigation chamber	Small mammal	Long-term	No data available. Not calculated. ¹	-

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	Endpoint	Toxicity (mg/l)
Laboratory tests				
‡ <i>Brachydanio rerio</i>	Sulfuryl fluoride	96 h	LC50	0.89
‡ <i>Daphnia magna</i>	Sulfuryl fluoride	48 h	EC50	0.62
‡ <i>Selenastrum capricornutum</i>	Sulfuryl fluoride	96 h	EbC50	0.58
Microcosm or mesocosm tests				
No data available				

¹ Exposure expected to be negligible

² Product is intended for use in enclosed buildings

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

Application rate (g as/m ³)	Crop ²	Organism	Time-scale	Distance (m)	TER ¹	Annex VI Trigger
128	Fumigation chamber	<i>Brachydanio rerio</i>	Acute	-	1939	100
128	Fumigation chamber	<i>Daphnia magna</i>	Acute	-	1350	100
128	Fumigation chamber	<i>Selenastrum capricornutum</i>	Acute	-	1264	10

Bioconcentration

Bioconcentration factor (BCF) ‡

Annex VI Trigger: for the bioconcentration factor

Clearance time (CT₅₀)
(CT₉₀)

Level of residues (%) in organisms after the 14 day depuration phase

Low potential for bioconcentration (Log P_{ow} 0.14 at 20 °C). Therefore as the Log P_{ow} is ≤ 3 a study is not required

Not required

Not required

Not required

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

Acute oral toxicity ‡

Acute contact toxicity ‡

No data available. Not required.

No data available. Not required.

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

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
No data available – exposure expected to be negligible				
Field or semi-field tests				
No data available – exposure expected to be negligible				

¹ Exposure expected to be negligible

² Product is intended for use in enclosed buildings

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

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
No data available – exposure expected to be negligible						
Field or semi-field tests						
No data available – exposure expected to be negligible						

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡

No data available – exposure expected to be negligible

Reproductive toxicity ‡

No data available – exposure expected to be negligible

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡

No data available – exposure expected to be negligible

Carbon mineralization ‡

No data available – exposure expected to be negligible

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data

Active substance
R50 Very toxic to aquatic organisms

Impact on Human and Animal Health

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

Rate and extent of absorption ‡	Rapidly absorbed via inhalation exposure (nose only), achieving maximum concentrations of ³⁵ S-sulfuryl fluoride-derived radioactivity in both plasma and red blood cells near the end of the 4-hr exposure period. The absorbed dose was estimated to be 14% at 30 ppm and 11% at 300 ppm
Distribution ‡	Seven days post-exposure, the ³⁵ S was not localised to any specific target or non-target tissue.
Potential for accumulation‡	Increased intake of fluoride may lead to fluorosis (i.e. accumulation of fluoride in bones and teeth)
Rate and extent of excretion ‡	Rapidly excreted, primarily via the urine. A large portion of the absorbed ³⁵ S was excreted in the urine even during the 4-hour exposure period.
Metabolism in animals ‡	Sulfuryl fluoride is first hydrolysed to fluorosulfate, with release of fluoride, followed by further hydrolysis to sulfate and release of the remaining fluoride.
Toxicologically significant compounds (animals, plants and environment) ‡	Parent and fluoride ion.

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral ‡	ca. 100 mg/kg T, R25
Rat LD ₅₀ dermal ‡	No adverse effects from 40.3 mg/litre (4 hour exposure)
Rat LC ₅₀ inhalation ‡	4.1-4.7 mg/litre (4 hour exposure)
Mouse LC ₅₀ inhalation	1.668 - 2.802 mg/litre (4 hour exposure): Toxic; R23 Toxic by Inhalation
Skin irritation ‡	No data (not required)
Eye irritation ‡	No data (not required)
Skin sensitization (test method used and result) ‡	No data submitted, but use experience has show no adverse effects with respect to this endpoint.

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Local effect on respiratory tract in all species (Brain – vacuolation in cerebrum (rat/dog/mouse) Kidney - mild hyperplasia (rat) Brain – minimal vacuolation & gliosis (dog) R48/20 Harmful: danger of serious damage to health by prolonged exposure through
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Lowest relevant oral NOAEL / NOEL ‡

Lowest relevant dermal NOAEL / NOEL ‡

Lowest relevant inhalation NOAEL / NOEL ‡

inhalation.
None (no data, not required)
None (no data, not required)
100 ppm (rat) 20 ppm (dog) (80 ppm for systemic toxicity rather than local irritation) 30 ppm (rabbit) 30 ppm (mouse)

Genotoxicity (Annex IIA, point 5.4) ‡

Overall, no genotoxic potential

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

Target/critical effect ‡

Kidney – renal failure (rat)
Respiratory tract - increases in aggregates of alveolar macrophages (rat)
Brain – minimal vacuolation of cerebrum (mouse)

Lowest relevant NOAEL / NOEL ‡

20 ppm (both species)

Carcinogenicity ‡

No evidence of carcinogenicity

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡

Reproduction: none
Parental toxicity increased incidence of spontaneous alveolar macrophages
Offspring: ↓ bodyweight

Lowest relevant reproductive NOAEL / NOEL ‡

Reproduction: 150 ppm (top dose)
Parental toxicity 5 ppm
Offspring: 20 ppm

Developmental target / critical effect ‡

Rabbit: reduced litter weights
Not teratogenic in rat or rabbit

Lowest relevant developmental NOAEL / NOEL ‡

Parental and developmental: 75 ppm

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7) ‡

Acute, 2-day (two 6-hr exposures in 30 hrs)
neurotoxicity study in female F344 rats

.....

13-week (6-hr exposures, 5 days/week)
neurotoxicity study in male and female F344
rats

12-month (6-hr exposures, 5 days/week)
neurotoxicity study in male and female F344
rats (part of two year study)

Acute

No effects at the highest concentration tested. The NOEL 300 ppm.

13-week

The primary effects were mild vacuolation of the brain and slowing of visual, auditory and somatosensory evoked potentials in all animals at 300 ppm. Visual and somatosensory evoked potentials were significantly slower in female rats and auditory brainstem responses were possibly slower in males at 100 ppm, although not at the top dose of 300 ppm. The NOAEL 30 ppm.

12-month

No effects on the nervous system at the highest concentration tested. The NOAEL 80 ppm.

Other toxicological studies (Annex IIA, point 5.8) ‡

.....
....

No mechanistic data provided.

Medical data (Annex IIA, point 5.9) ‡

.....
....

In the USA, since 1993 there have been 335 reports of alleged human health effects associated with sulfuryl fluoride reported to the US EPA by Dow AgroSciences. There were 13 human deaths, primarily resulting from unauthorised entry into the tented fumigated structure. The majority (60%) of the non-fatal incidents involved symptoms of eye and respiratory irritation, sore throat and cough (justifying classification proposal R37); in some of these cases the symptoms may have been related to residual chloropicrin in the dwellings subsequent to ventilation and clearing of sulfuryl fluoride from the structure. The next most common (9%) complaint was flu-like symptoms of nausea, diarrhea, fever, and headache. Approximately 6% complained primarily of shortness of breath or respiratory distress.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.014 mg/kg/bw/day	2-year rat	100
AOEC ‡ (Operator/Worker)	1 ppm	Mouse 90 day inhalation study	100
AOEC ‡ (Bystander)	3 ppm	Rat acute neurotoxicity	100
ARfD (acute reference dose) ‡	0.7 mg/kg bw	acute neurotoxicity study	100

* Based on estimates of inhalational exposure over the 4 hour exposure periods in the ADME study and actual 'dose received' (radioactivity in urine, faeces and tissues) the absorbed dose was estimated to be 14% at 30 ppm and 11% at 300 ppm. Therefore NOAEL corrected by a factor of 0.1 to account for this.

Dermal absorption (Annex IIIA, point 7.3) ‡

.....	no data – not required.
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Acceptable exposure scenarios (including method of calculation)

Operator	Based on data from mill fumigation trials exposure below the AOEC is expected provided operators (fumigators) wear respiratory protective equipment (self-contained breathing apparatus, SCBA) when introducing and aerating the gas or on any occasion that air concentration of the gas is above 1 ppm. Under these conditions the long term exposure is not expected to exceed the AOEC of 1 ppm.
Workers	Fumigated structure must be cleared for re-entry following fumigation by operators (fumigators) and only when analytical equipment confirms levels of sulfuryl fluoride are < 1 ppm. In case of earlier re-entry SCBA has to be worn not to exceed the 1 ppm ...
Bystanders	Field data measurement indicate a 10 m exclusion zone around the fumigated structure to protect bystander (exposure levels < 3 ppm)

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	T, R23 Toxic by Inhalation R25 Toxic if swallowed R37 Irritating to respiratory system R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.
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Residues

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

Plant groups covered	No metabolism study on food items submitted (data requirement), Transfer studies on wheat flour, dog food, beef, cake, acetaminophen and oil
Rotational crops	No data submitted or required as the product is for use in the fumigation of the interior of buildings
Plant residue definition for monitoring	Sulfuryl fluoride and fluoride ion expressed individually (provisional, to be confirmed by data); bound fluoride residues may need to be included (open)
Plant residue definition for risk assessment	Sulfuryl fluoride and fluoride ion expressed individually (provisional, to be confirmed by data); bound fluoride residues may need to be included (open)
Conversion factor (monitoring to risk assessment)	1

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

Animals covered	No data were submitted or required, due to no uses being proposed on animal feed products.
Animal residue definition for monitoring	n/a
Animal residue definition for risk assessment	n/a
Conversion factor (monitoring to risk assessment)	n/a
Metabolism in rat and ruminant similar (yes/no)	n/a
Fat soluble residue: (yes/no)	No

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

.....	No data were submitted or required, due to only the interior of buildings being treated.
---------------	--

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

.....	<p>Sulfuryl fluoride - No data were submitted or required as the commodities were analysed on the day of sampling, being stored in a plastic between sampling and analysis.</p> <p>Fluoride - No data were perceived to be required as it was assumed that fluoride residues would be stable in the commodities. This was confirmed by</p>
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a study which indicated that residues of fluoride in wheat grain and flour, raisins, walnuts and maize grain and meal were stable for at least 1 month (length of study) at ambient temperatures and for at least 3 months (length of study) at -20°C .

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:

Muscle

Liver

Kidney

Fat

Milk

Eggs

Intake by livestock is not relevant due to uses not being proposed on animal feed products.³⁶

³⁶ contaminated and discarded cereal products must not be fed to livestock animals

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Flour mill	N S	<p>Germany, UK, USA (2002)</p> <p><u>Sulfuryl fluoride</u></p> <p>No analysis was perceived to be required based on indications</p> <p><u>Fluoride</u></p> <ul style="list-style-type: none"> - at initiation of full production: flour 4.9, 13, 61 mg/kg bran <4, 15, 90 mg/kg - after 60 minutes of full production: flour 2 x < 2, 1 x 2.7 mg/kg bran 3 x < 4 mg/kg 	<p>LOQ in the trials was 2 mg/kg in flour and 4 mg/kg in bran; New LOQ is 0.5 mg/kg.</p> <p>No agreed acceptable fluoride background levels available. Data requirement set</p>	-	-

(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 critical GAP

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

Note: Solely for the treatment scenario ‘detached empty grain store’ exposure of the consumer to residues is not expected.

For scenarios where contamination (‘passive fumigation’) of grain or cereal products may occur at fumigation of a structure, the following assessment is applicable:

ADI	Sulfuryl fluoride: 0.014 mg/kg bw/day Fluoride: open, not agreed during peer review
TMDI (European Diet) (% ADI)	
NEDI (% ADI)	Sulfuryl fluoride – no consumer exposure estimates available, chronic RA not conducted Fluoride - measures proposed to discard and blend flour or bran exposed to sulfuryl fluoride to reach natural fluoride background level, however no supportive data available RA not finalised
Factors included in NEDI	None
ARfD	Sulfuryl fluoride: 0.6 mg/kg bw/day Fluoride: open, not agreed during peer review
Acute exposure (% ARfD)	Sulfuryl fluoride – no consumer exposure estimates available, acute RA not conducted Fluoride - measures proposed to discard and blend flour or bran exposed to sulfuryl fluoride to reach natural fluoride background level, however no supportive data available RA not finalised

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

None of the treated commodities are processed further.

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

No agreed MRLs proposals are available.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
Sulfuryl fluoride		$\begin{array}{c} \text{O} \\ \parallel \\ \text{F}-\text{S}-\text{F} \\ \parallel \\ \text{O} \end{array}$
Fluorosulfonic acid		$\begin{array}{c} \text{O} \\ \parallel \\ \text{F}-\text{S}-\text{OH} \\ \parallel \\ \text{O} \end{array}$
Sulfate		$\begin{array}{c} \text{O}^- \\ \\ \text{O}=\text{S}=\text{O} \\ \\ \text{O}^- \end{array}$
Fluorhydric acid (hydrofluoric acid)		HF

ABBREVIATIONS

ADI	acceptable daily intake
AOEC	acceptable operator exposure concentration
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
CTP	Concentration x time product
d	day
DAR	draft assessment report
DM	dry matter
DT ₅₀	period required for 50 percent dissipation (define method of estimation)
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
ϵ	decadic molar extinction coefficient
EC ₅₀	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GC-TCD	gas chromatography with thermal conductivity detector
GS	growth stage
GWP	Global warming potential
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JPMR	Joint meeting on pesticide residues
K _{oc}	organic carbon adsorption coefficient
kg	kilogram

L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC ₅₀	lethal concentration, median
LD ₅₀	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
m	metre
mg	milligram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
ng	nanogram
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC _A	predicted environmental concentration in air
PEC _S	predicted environmental concentration in soil
PEC _{SW}	predicted environmental concentration in surface water
PEC _{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK _a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
r ²	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
TRR	Total Radioactive Residues
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year