Human Health Bystander Screening Level Analysis: Volatilization of Conventional Pesticides

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Section 1.0: Introduction

Over many years, the Environmental Protection Agency (the Agency) has been actively engaged in evaluating possible exposures associated with air borne, off-target movement of pesticides. This has included developing and refining its methodologies for assessing bystander exposures resulting from volatilization of fumigants as well as exposure to spray drift[1] from the application of conventional pesticides in agricultural settings. More recently, the Agency has been adapting the approaches developed for conducting risk assessments for the fumigants for use in assessing potential bystander inhalation risk resulting from the volatilization of other conventional pesticides (i.e., non-fumigants). Notable milestones in this effort include the 2009 FIFRA Scientific Advisory Panel (SAP) [2] review of issues related to volatilization of conventional pesticides and the 2013 chlorpyrifos volatility assessment[3].

The Agency has recently developed a Volatilization Screening Tool that provides a consistent and health protective framework to assess the potential inhalation bystander risks resulting from volatilization of conventional pesticides. In addition, a Volatilization Screening Tool Guidance Document (see Appendix A) was produced to support the screening tool. The screening tool utilizes a number of physical and chemical properties to predict flux (i.e., the rate at which a chemical volatilizes off of a treated field); the AERSCREEN[4] model to estimate air concentrations at different distances from a treated field; and chemical-specific human health toxicological data to estimate potential bystander inhalation risks. This document provides details on the volatilization screening methodology including the development of the screening tool, the guiding principles behind the screening tool, and the various inputs utilized in the screening tool. It also presents the results of the screening analysis that the Agency has recently completed using this methodology which examined all of the conventional pesticides being evaluated in the Registration Review[5] process. The Agency plans to use the results of the screening analysis to determine when volatilization data (i.e., flux studies) and/or route-specific inhalation toxicological data (if not already available) should be required for a chemical.

Section 2: Volatilization Screening Tool Development provides a brief discussion of the development of the volatilization screening tool as well as a discussion of the guiding principles behind the screening tool. ***Section 3: Volatilization Screening Tool Inputs*** outlines the inputs used to populate the volatilization screening tool. ***Section 4: Registration Review Chemical Volatilization Screen Results*** discusses the results of the Agency's volatilization analysis for the conventional Registration Review chemicals. ***Section 5: Registration Review Chemical Volatilization Screen Characterization*** discusses issues that should be considered when interpreting the volatilization analysis for the Registration Review chemicals.

[1] Reference Spray Drift Doc once final
[2] 2009 Volatilization SAP: http://www.regulations.gov/ (EPA-HQ-OPP-2009-0687)
[3] 2013 Chlorpyrifos Volatility Assessment: http://www.regulations.gov/ (EPA-HQ-OPP-2008-0850)
[4] http://www.epa.gov/ttn/scram/dispersion_prefrec.htm
[5] http://www.epa.gov/oppsrrd1/registration_review/

Section 2.0: Volatilization Screening Tool Development

In order to assess the potential inhalation bystander risks resulting from volatilization of conventional pesticides in a consistent and health protective manner, a volatilization screening tool has been developed. This screening tool can be used to estimate upper bound, health protective air concentrations at various distances from a treated field resulting from the volatilization of conventional pesticides. Prior to development of this screening tool, the Agency typically used the Probabilistic Exposure and Risk model for FUMigants (PERFUM) for conducting bystander inhalation screening assessments. Use of PERFUM[6] is resource intensive and requires the input of emission rate profiles (gathered from field volatility studies) that are not typically available for conventional pesticides.

Given these issues, a need was identified for a tool that was less resource and data intensive but still resulted in health protective risk estimates. The volatilization screening tool utilizes three main inputs in assessing the potential inhalation bystander risks from conventional pesticides. First, physical and chemical properties are used to predict flux based on the work by Woodrow *et al.* (1997)[7] and Woodrow *et al.* (2001)[8]. Second, the screening tool uses the estimated flux along with the AERSCREEN[9] model to estimate air concentrations at different distances from the treated field. [Note: AERSCREEN is used routinely for regulatory air permitting and has undergone extensive review as described in the associated background materials.] Finally, the air concentrations are compared to chemical-specific human health toxicological data to estimate potential bystander inhalation risks. All of these components are combined into a simple to use Excel workbook. Users must have Microsoft Excel 2007 or higher in order to use the screening tool. In addition, the tool also uses Visual Basic functions, so users must enable macros in order to use the tool. Figure 1 provides a screen shot of the Volatilization Screening Tool.

[6] http://www.exponent.com/ProjectDetail.aspx?project=450

[7] Woodrow, J., Seiber, J., Baker, L. 1997. *Correlation Techniques for Estimating Pesticide Volatilization Flux and Downwind Concentrations*. Environ. Sci. Technol., 31:523-529

[8] Woodrow, J., Seiber, J., Dary, C. 2001. *Predicting Pesticide Emissions and Downwind concentrations Using Correlations with Estimated Vapor Pressures*. J. Agric. Food Chem. 49:3841-3846

[9] http://www.epa.gov/ttn/scram/dispersion_prefrec.htm

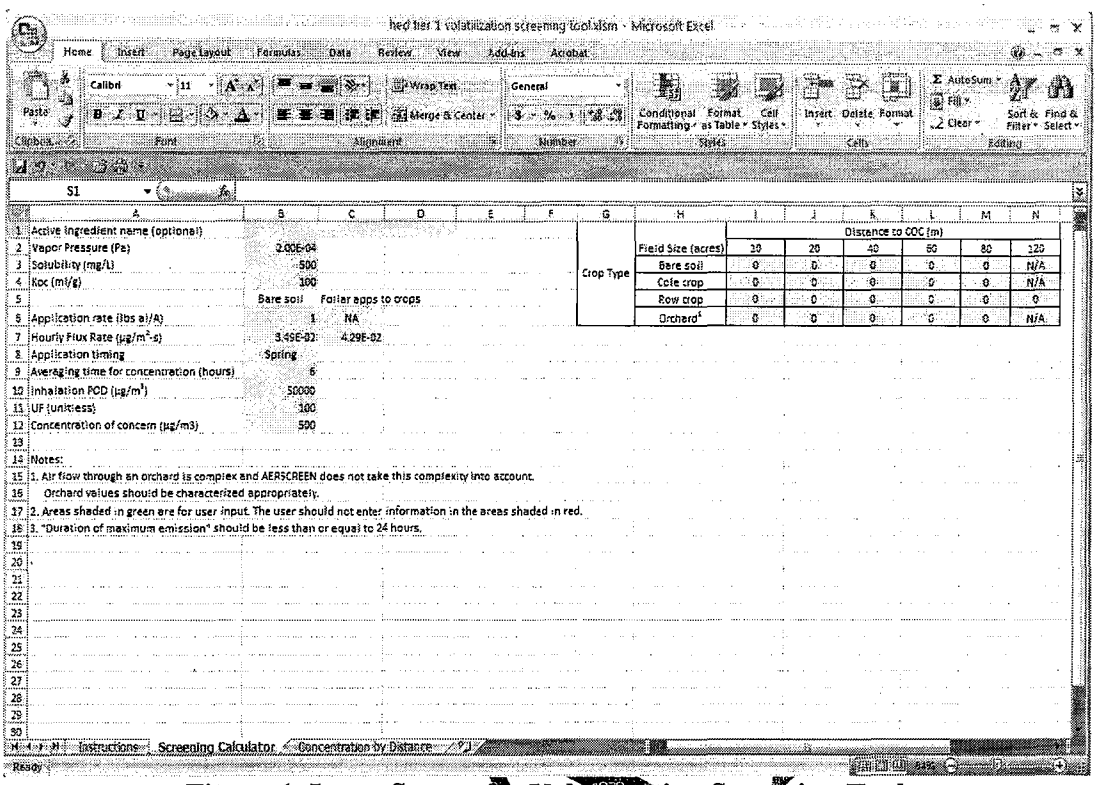

Figure 1. Input Screen for Volatilization Screening Tool

More specific details on the use of a modified Woodrow equation and the AERSCREEN model in the Volatilization Screening Tool are presented below. Specific details on the physical and chemical properties and toxicological inputs used in the Volatilization Screening Tool are presented in Section 3.0.

Modified Woodrow Equation

At the 2009 FIFRA Scientific Advisory Panel (SAP) [10] related to volatilization of conventional pesticides, the Agency presented multiple methods for estimating emissions released from a pesticide-treated field. The approach defined in Woodrow *et al* (1997) and Woodrow *et al* (2001) was one of the methods presented to the Panel. The Panel commented that the Woodrow approach would be a good starting point for a Tier I, screening level approach. In these two papers, the study authors developed a linear relationship between the natural logarithm of a chemical's physical and chemical properties to the natural logarithm of the amount of chemical emitted from soil or a plant surface. However, like all linear relationships, half of the emissions were underestimated when compared to the measured values used to derive the relationship. In order to be conservative and health protective, the Agency used the data provided in the Woodrow *et al* (1997) to construct an alternative linear model using the 90% lower confidence limit of the slope and 90% upper confidence limit of the intercept as the model parameters. The results of the regressions are presented in the Volatilization Screening Tool Guidance Document (see Appendix A).

[10] 2009 Volatilization SAP: http://www.regulations.gov/ (EPA-HQ-OPP-2009-0687)

For **soil applied** pesticides, the following equation can be used to derive a flux rate:

$$flux = e^{(0.8688R+21.535)}/3600$$

$$R = \ln\left(\frac{\text{VP x AR}}{\text{Sol x } K_{OC}}\right)$$

Where:

flux = flux rate (μg/m^2-s),
VP = vapor pressure (Pa),
AR = application rate (lb/A),
Sol = solubility (mg/L), and
Koc = organic carbon sorption coefficient (ml/g).

For **foliar applied** pesticides, the following equation can be used to derive a flux rate

$$flux = e^{(0.8268\ln(VP)+12.081)}/3600$$

Where:

flux = flux rate (μg/m^2-s), and
VP = vapor pressure (Pa).

Note: In Woodrow *et al* (1997), pesticide residues on plant surfaces were assumed to be volatilizing from a non-interactive surface in the period just after application and a very good correlation between flux and vapor pressure was obtained for a dozen compounds. An attempt was made to develop an equation that incorporates application rate for foliar applied pesticides however the Agency was unable to obtain a good correlation for this equation.

AERSCREEN Model

AERSCREEN is a screening air model based on AERMOD[11], which is an air quality model that incorporates air dispersion based on planetary boundary layer turbulence structure and scaling concepts, including treatment of both surface and elevated sources, and both simple and complex terrain. AERMOD was developed as a joint effort between the American Meteorological Society and the EPA. In 1998, a formal peer review of the model was performed[12]. An independent model evaluation was also completed in 1998[13,14]. AERMOD is currently a recommended EPA air model as per Appendix W[15] of 40 CFR Part 51.

AERSCREEN produces estimates of "worst-case" 1-hour concentrations for a single source without the need for site specific hourly meteorological data. The Volatilization Screening Tool was developed using a limited number of AERSCREEN model runs, at a standard flux rate of $1x10^{-6}$ g/m^2-s, for various field sizes, crop scenarios, seasons of application, and meteorological conditions. The results of these AERSCREEN model runs were then imported into the Excel screening tool. The Volatilization Screening Tool Guidance Document details the input parameters used in the AERSCREEN model runs (see Appendix A).

EPA air screening guidance from 1992 does not recommend calculation of air concentrations beyond 1 hour periods to different exposure periods for field source emissions (*e.g.*, 8-hour time weighted air concentration)[16]. However, a peak-to-mean scaling factor has been developed, based on runs done in PERFUM, to allow estimation of concentrations for averaging periods longer than one hour, but less than 24 hours in order to match the duration of the potential exposure period to a period similar to that used for defining the toxicological level of concern (e.g., 6 hour inhalation dose administration in a rodent study is typical). The Agency notes that PERFUM received a favorable review by the FIFRA SAP in 2004[17] and since that time the Agency has consistently used it in the assessment of the fumigants. The Volatilization Screening Tool Guidance Document details the specifics of the peak-to-mean scaling factor (see Appendix A).

In AERSCREEN, air concentrations are directly related to the emission rate from a field. The Volatilization Screening Tool scales the results from the AERSCREEN runs, using the application rate and physical and chemical properties of the pesticide to estimate flux, to estimate off-field air concentrations for a variety of crop scenarios and meteorological conditions. The Volatilization Screening Tool provides estimates of the distance from the edge of the field where air concentrations fall below the concentration of concern for a chemical. In this way, the

[11] http://www.epa.gov/ttn/scram/dispersion_prefrec.htm#aermod

[12] United States Environmental Protection Agency. Compendium of http://www.epa.gov/scram001/7thconf/aermod/dockrpt.pdf. Accessed March 2002.

[13] Paine, R.J, R.F. Lee, R. Brode, R.B. Wilson, A.J. Cimorelli, S.G. Perry, J.C. Weil, A.Venkatram, and W. Peters. Model Evaluation Results for AERMOD.

[14] Paine. R., R. Lee, R. Brode, R. Wilson, A. Cimorelli, S. Perry, J.Weil, A. Venkatram, W. Peters. AERMOD: Model Formulation and Evaluation Results. Preprints, *92th Annual Meeting of Air and Waste Management Association,* Air and Waste Management Association, Pittsburgh, PA. (1999)

[15] http://www.epa.gov/ttn/scram/guidance/guide/appw_05.pdf

[16] U.S. EPA, 1992: Screening Procedures for Estimating the Air Quality Impact of Stationary Sources. EPA-454/R-92-019. U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

[17] http://www.epa.gov/scipoly/sap/meetings/2004/082404_mtg.htm

Volatilization Screening Tool can be used to easily eliminate the inhalation pathway for pesticides not posing a risk of concern to bystanders following applications.

Section 3.0: Volatilization Screening Tool Inputs

As described in Section 2, the Volatilization Screening Tool consists of three major components, the modified Woodrow Equation, AERSCREEN, and chemical-specific human health toxicological data. In order to run the screen, a number of input parameters must be utilized (see Figure 1 above). These parameters include a number of physical/chemical properties, application scenarios, application rate, application timing, and human health toxicological data. These inputs were obtained or derived from a number of sources. In many cases, physical/chemical properties and toxicological information for individual chemicals were publicly available in Agency exposure and risk assessment documents and were defined based on guideline studies intended for this purpose. However, in some cases, it was necessary to find or verify the physical/chemical properties of a chemical via other reliable internet resources. In addition, application scenarios, application rate, and application timing were obtained from pesticide labels. The following sections will discuss the details of each specific input parameter for the Volatilization Screening Tool.

Vapor Pressure (Pa)

Vapor pressure is the pressure exerted by a vapor in equilibrium with its solid or liquid state. Chemicals with higher vapor pressures are more likely to transform to the gaseous stage and volatilize off of treated fields. The modified Woodrow equation utilizes vapor pressure for both the soil and foliar surface flux equations (see Section 2).

Solubility (mg/L)

Solubility is the ability of a substance to dissolve in solution. Chemicals with higher solubility have a greater likelihood to remain in solution and not volatilize. The modified Woodrow equation utilizes solubility only in the soil surface flux equation (see Section 2).

K_{oc} (ml/g)

K_{oc} refers to the soil organic carbon-water partitioning coefficient. It is the ratio of the mass of a chemical that is absorbed in the soil per unit mass of organic carbon in the soil per the equilibrium chemical concentration in the solution. K_{oc} is useful when predicting the mobility of organic soil contaminants; higher K_{oc} values correlate to less mobile organic chemicals and lower K_{oc} values correlate to more mobile organic chemicals. All other parameters being equal, chemicals with lower K_{oc} values have a greater likelihood to volatilize from soil since they have less of an affinity to adsorb to the soil. The modified Woodrow equation utilizes K_{oc} only in the soil surface flux equation (see Section 2).

Maximum Single Application Rate (lb ai/A)

The modified Woodrow equation utilizes application rate only in the soil surface flux equation (see Section 2). As a result, maximum application rate in the screening tool refers to the maximum labeled application rate for broadcast soil directed applications. The maximum application rate is chosen in order to be protective of all labeled broadcast soil directed application rates.

Application Timing

Application timing refers to when the pesticide is applied during the year. The screening tool allows for selection of winter, spring, summer, or fall for the timing of application. The application timing impacts the outputs of the AERSCREEN model runs that the Volatilization Screening Tool utilizes. The model runs are impacted by application timing via a variety of factors such as temperature, albedo, Bowen ratios, surface roughness, and release height. These are discussed in more detail in the Volatilization Screening Tool Guidance Document (see Appendix A). For the screening analysis, the Agency chose to use spring as the default application timing because it represents the most likely season of application.

Crop Scenario

The screening tool generates results for four different crop height scenarios that are labeled as bare soil, cole, row, and orchards[18]. The crop scenarios included in the screening tool are not a true input, but rather a built-in feature of the screening tool. These scenarios are designed to cover the range of potential release heights (i.e., crop canopy heights) that are most commonly associated with semi-volatile applications. Results for bare soil represent applications to soil prior to or at planting crops. Results for cole crops represent foliar applications to low growing crops (i.e., about 3 feet or less) such as soybeans, strawberries, cabbage, and some vegetables. Results for row crops represent foliar applications to medium growing crops (i.e., 6 to < 18 feet) such as corn and tomatoes. Results for orchard crops represent foliar applications to orchard crops (i.e., > 18 feet) such as apples or oranges. Crop scenario also impacts the potential size of the source field as acres treated can be impacted by the type of crop or application equipment used to treat that crop.

Averaging time for concentration (hours)

The averaging time for concentration input is defined based on the toxicological data for a chemical, and refers to the length of time the study animal was exposed in the study used to select the inhalation endpoint. In all cases, the Agency attempts to match the duration over which the estimated air concentrations (i.e., exposures) are averaged with the duration the animal was exposed in the toxicological study. For example, if a rat inhalation study is used where the rat was exposed for 4 hours a day, 4 hours would be input for the exposure concentration averaging time in the screening tool. As a default, 6 hours (i.e., the typical duration of exposure in many route-specific toxicological studies as described in Agency guidelines) was used as the averaging time in all cases where an oral study was used as the basis for the inhalation endpoint. Due to the importance of averaging time, a peak-to-mean scaling factor was developed (as discussed in Section 2 above) to allow estimation of concentrations for averaging periods longer than the one hour AERSCREEN outputs (Appendix A).

[18] Air flow through an orchard is complex and AERSCREEN does not take this complexity into account. Orchard values should be characterized appropriately.

Inhalation Point of Departure (POD) ($\mu g/m^3$)

Inhalation POD refers to the chemical-specific human-health point of departure selected for the inhalation route of exposure in a chemical's most recent human health exposure or risk assessment. For this input, there are three options and all three of these were used in the Registration Review chemical volatilization screening analysis:

- If, in the most recent, relevant risk assessment, a route-specific inhalation toxicological study was used as the basis for the inhalation endpoint and a human equivalent concentration (HEC) was calculated via use of the Agency's reference concentration (RfC) methodology,[19] the Agency used the HEC for the inhalation POD.
- If, in the most recent, relevant risk assessment, a route-specific inhalation toxicological study was used as the basis for the inhalation endpoint, but an HEC was not calculated, the Agency used the no observed adverse effect level (NOAEL) for the inhalation POD. [Note: In the future, HECs could be calculated for these chemicals.]
- If, in the most recent, relevant risk assessment, a route-specific inhalation toxicological study is not available and, thus, an oral toxicological study was used as the basis for the inhalation endpoint, the Agency used the NOAEL from the oral study, converted to an inhalation equivalent concentration (IEC) via the following equation.

$$IEC = \frac{NOAEL \times CF1}{A \times CF2 \times D \times AF}$$

Where:

IEC = inhalation equivalent concentration ($\mu g/m^3$),
NOAEL = NOAEL from oral study (mg/kg/day),
CF1 = conversion factor to convert mg to µg,
A = absorption (unitless),
CF2 = conversion factor to account for species specific respiratory volume and body weight (m^3/hr/kg),
D = duration (hrs/day), and
AF = activity factor (unitless).

Subsequently, the IECs were used for the inhalation POD in the screening tool. The IECs used in the Registration Review chemical screen can be found in Appendix B.

Uncertainty Factor (UF) (unitless)

Uncertainty factor refers to the total uncertainty factors applied to an individual chemical. Uncertainty factors can be applied for a variety of reasons including, but not limited to, interspecies factor, intraspecies factor, FQPA (Food Quality Protection Act) factor, LOAEL to NOAEL factor, database uncertainty factor, etc.

[19] U.S. EPA. Methods for Derivation of Inhalation Reference Concentrations (RfCs) and Application of Inhalation Dosimetry. U.S. Environmental Protection Agency, Office of Research and Development, Office of Health and Environmental Assessment, Washington, DC, EPA/600/8-90/066F.

For the Registration Review chemical screening analysis, the following uncertainty factors were used:

- Route-specific inhalation study; HEC calculated:
  - UF for interspecies extrapolation may be reduced to 3X per the RfC methodology;
  - UF for intraspecies variation was retained at 10X; and
  - Additional UFs were applied consistent with the most recent, relevant risk assessment for each chemical (e.g., FQPA, LOAEL to NAOEL, etc.).
- Route-specific inhalation study; HEC not calculated:
  - UF for interspecies extrapolation was retained at 10X;
  - UF for intraspecies variation was retained at 10X; and
  - Additional UFs were applied consistent with the most recent, relevant risk assessment for each chemical (e.g., FQPA, LOAEL to NAOEL, etc.).
- Oral study; IEC calculated:
  - UF for interspecies extrapolation was retained at 10X;
  - UF for intraspecies variation was retained at 10X;
  - FQPA UF of 10X to address database uncertainty due to lack of an inhalation study was applied consistent with current Hazard and Science Policy Council (HASPOC) policies; and
  - Additional UFs were applied consistent with the most recent, relevant risk assessment for each chemical (e.g., FQPA, LOAEL to NAOEL, etc.).

Section 4.0: Registration Review Chemical Volatilization Screen Results

All pesticides distributed and sold in the United States must be registered by the Agency, based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. Registration Review is a process that makes sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects.[20] To ensure that the potential for exposure via volatilization from all impacted pesticides are considered under this process, the tools described above were used to perform a bystander inhalation screening analysis for all of the conventional Registration Review chemicals. Appendix C contains the input sheets for the Volatilization Screening Tool for every chemical screened. The Agency plans to use the results of this screening analysis to determine when volatilization data (i.e., flux studies) and/or route-specific inhalation toxicological data (if not already available) should be required for a chemical.

The analysis consisted of screening 427 chemicals. There were three basic outcomes of the screen: no quantitative screen, pass the quantitative screen, and fail the quantitative screen. These outcomes are described in further detail below.

[20] http://www.epa.gov/oppsrrd1/registration_review/index.htm

- A quantitative screen was not performed for 174 chemicals. In all cases, these chemicals have no wide-scale, agricultural uses. For pesticides that did not receive a quantitative screen, the Agency has high confidence that use of the pesticide will not result in any meaningful bystander risk due to volatilization of residues based on a variety of specific reasons which are provided in Appendix D. In general, the categories of reasons for not performing a quantitative screen include the following:
  - 22 of these chemicals will have qualitative risk assessments during Registration Review;
  - 21 of these chemicals either have no currently registered products or have been voluntarily cancelled as part of Registration Review;
  - 12 of these chemicals have inhalation toxicity studies that show no effects;
  - 18 of these chemicals are classified as fumigants and thus volatilization is the major route of exposure and is already assessed or will be assessed during Registration Review;
  - 12 of these chemicals have uses that will result in separate post-application inhalation assessments (e.g., indoor, mosquito adulticide uses);
  - 65 of these chemicals are registered for uses that are not expected to have any significant potential for volatilization:
    - 8 only registered for direct aquatic application uses;
    - 18 are only registered as baits;
    - 6 are only registered for greenhouse use;
    - 5 are only registered for direct animal application uses (e.g., pet, livestock uses);
    - 5 are only registered for seed treatment uses;
    - 6 are only registered for repellent uses;
    - 10 of these chemicals have import tolerances only and thus have no registered uses in the U.S.;
    - 7 are only registered for other unique uses (e.g., post-harvest treatments, food handling establishments, tree injection, etc.)
  - 24 of these chemicals have registered uses (e.g., residential turf, ornamentals) that cannot be screened with the Volatilization Screening Tool. The potential for these chemicals to volatilize will be dealt with on an individual chemical basis throughout Registration Review.

- 185 chemicals passed the quantitative screen. Passing the quantitative screen means that the concentration of concern (i.e., the point of departure divided by the total uncertainty factors or COC) was not exceeded for any crop scenario at any distance downwind from any size field. For a pesticide that passed the screening analysis, the Agency has high confidence that use of the pesticide will not result in any meaningful bystander risk due to volatilization of residues and further data would generally not be required.

- 68 chemicals failed the quantitative screen. Failing the quantitative screen means that the COC was exceeded for at least one crop scenario at some distance downwind from the field for at least one field size. Of the chemicals that failed the quantitative screen, 24 have route-specific inhalation toxicological data, while 44 do not. There are 53 occurrences of a foliar application failing the screen and 24 occurrences of a soil

application failing the screen (i.e., some chemicals have multiple crop scenarios that fail). If a pesticide fails the screening analysis, the Agency would examine whether data are available to refine the analysis and whether additional data should be required. Failing the screening analysis does not necessarily mean that the pesticide poses a risk of concern due to volatilization. Rather, due to the purposely conservative nature of the screening analysis (see Section 5.0), failing the screen is merely a trigger for the Agency to further investigate the question of exposure from volatilization of the pesticide. Potential additional data that could help to refine a failing screen include the following:

- volatilization data (i.e., flux studies);
- route-specific inhalation toxicological data if none are available; and/or
- vapor-phase dose administration inhalation toxicological data if only aerosol dose administration inhalation toxicological data are available.

Table 1 presents the details of the 68 chemicals that failed the quantitative screen. In addition, Appendix D provides details on the screen for the entire 427 chemicals.

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Table 1: Registration Review Chemicals that Fail the Quantitative Volatilization Screen Analysis		
Chemical	**Inhalation Tox Study Available?**	**Comments**
Acephate	Yes	Cole and row scenarios exceed COC at 20 acre and larger fields.
Acibenzolar	No	Cole scenario exceeds COC at 60 acre and larger fields.
Atrazine	No	Soil scenario exceeds COC at all field sizes.
Bromoxynil and esters	No	Cole and row scenarios exceed COC at 60 acre and larger fields.
Buprofezin	No	Cole and orchard scenarios exceed at all field sizes.
Butylate	No	Soil scenario exceeds COC at all field sizes. All applications soil incorporated, likely conservative.
Captan	Yes	Cole, row, and orchard scenarios exceed COC at all field sizes.
Chlorethoxyfos	Yes	Row scenario exceeds COC at all field sizes.
Chlorothalonil	Yes	Cole, row, and orchard scenarios exceed COC at all field sizes.
Chlorpropham	No	Cole scenario exceeds COC at all field sizes. Only "agricultural" use is Easter lilies which are only grown in Norther CA and Southern OR.
Chlorpyrifos	Yes	Cole, row, orchard scenarios exceed COC at all field sizes.
Daminozide (Alar)	No	Row scenario exceeds COC at all field sizes.
DCNA	No	Cole and row scenarios exceed COC at 20 acre field sizes and larger.
Diazinon	Yes	Cole, row, orchard scenarios exceed COC at all field sizes.
Dicamba	No	Cole and row scenarios exceed COC at 40 acre field sizes and larger.
Dichlobenil	Yes	Row and orchard scenarios exceed COC at all field sizes.
Dicrotophos	Yes	Cole scenario exceeds COC at all field sizes.
Dimethenamid	No	Cole and soil scenarios exceed COC at all field sizes.
Dimethoate	Yes	Cole, row and orchard scenarios exceed COC at all field sizes.
Diquat Dibromide	Yes	Cole and row scenarios exceed COC at all field sizes. Orchard scenario exceeds COC at 80 acre field sizes and larger.
Emamectin Benzoate	No	Cole scenario exceeds COC at 60 acre field sizes and larger.
Endothall, and salts	No	Cole and row scenarios exceed COC at all field sizes.
EPTC	Yes	Cole and row scenarios exceed COC at all field sizes.

Table 1: Registration Review Chemicals that Fail the Quantitative Volatilization Screen Analysis		
Chemical	**Inhalation Tox Study Available?**	**Comments**
Esfenvalerate	No	Row scenario exceeds COC at 60 acre field sizes and larger.
Ethalfluralin	No	Soil, cole, and row scenarios exceed COC at all field sizes.
Ethofumesate	No	Soil scenarios exceed COC at all field sizes.
Ethoprop	No	Soil scenario exceeds COC at all field sizes. All applications soil incorporated, likely conservative.
Fenpropathrin	No	Row scenario exceeds COC at 120 acre field size only.
Ferbam	No	Cole scenario exceeds COC at 20 acre field sizes and larger.
Flumetsulam	No	Soil scenario exceeds COC at 20 acres and larger.
Flumioxazin	No	Soil, cole, and row scenarios exceed COC at all field sizes.
Fomesafen	No	Soil scenarios exceed COC at all field sizes.
Formetanate HCl	No	Row and orchard scenarios exceed COC at all field sizes.
Fosthiazate	Yes	Row scenarios exceed COC at all field sizes.
Linuron	No	Soil, cole, and row scenarios exceed COC at all field sizes.
MCPA	No	Soil and cole scenarios exceed COC at most field sizes.
Metalaxyl	No	Cole and row scenarios exceed COC at 60 acre field sizes and larger.
Methamidophos	Yes	Cole and row scenarios exceed COC at all field sizes.
Metolachlor & s-Metolachlor	No	Cole and row scenarios exceed COC at 60 acre field sizes and larger.
Metsulfuron	No	Row scenario exceeds COC at 40 acre field sizes and larger.
Naled	Yes	Cole, row, and orchard scenarios exceed COC at all field sizes.
Nitrapyrin	No	Row scenarios exceed COC at all field sizes.
Paraquat dichloride	Yes	Cole and row scenarios exceed COC at all field sizes.
PCNB	No	Cole, row, orchard, and soil scenarios exceed COC at all field sizes.
Pendimethalin	No	Soil, cole, row, and orchard scenarios exceed COC at all field sizes.
Phorate	No	Soil scenario exceeds COC at all field sizes. Note: Granular products only. All applications soil incorporated, likely conservative.
Phosmet	No	Cole and row scenarios exceed COC at all field sizes.

Table 1: Registration Review Chemicals that Fail the Quantitative Volatilization Screen Analysis		
Chemical	**Inhalation Tox Study Available?**	**Comments**
Pronamide	No	Soil, cole, and row scenarios exceed COC at all field sizes.
Propachlor	No	Soil scenarios exceed COC at all field sizes.
Propazine	No	Soil scenario exceed COC at 60 acre field sizes and larger.
Pyrethrin and derivatives	Yes	Cole and row scenarios exceed COC at 40 acre field sizes and larger.
Pyridaben	Yes	Cole scenario exceeds COC at 40 acre field sizes and larger.
Pyrimethanil	No	Cole scenario exceeds COC at 40 acre field sizes and larger.
Simazine	No	Soil scenario exceeds COC at 40 acre field sizes and larger.
Tebupirimiphos	Yes	Soil and row scenarios exceed COC at all field sizes.
Tefluthrin	Yes	Soil scenario exceeds COC at all field sizes.
Terbacil	No	Row scenario exceeds COC at 120 acre field size only.
Terbufos	Yes	Soil scenario exceeds COC at all field sizes. Note: Granular products only. All applications soil incorporated, likely conservative.
Tetraconazole	Yes	Cole, row, and orchard scenarios exceed COC at all field sizes.
Thiazopyr	No	Soil scenario exceeds COC at all field sizes.
Thiobencarb	No	Soil scenario exceeds COC at all field sizes.
Thiodicarb	Yes	Cole and row scenarios exceed COC at all field sizes. Note: Inhalation study is on dust formulation.
Thiophanate-methyl	No	Cole and row scenarios exceed COC at 40 acre field sizes and larger.
TPTH (Triphenyltin hydroxide)	Yes	Cole and row scenarios exceed COC at all field sizes. Orchard exceed COC at 40 acre field sizes and larger.
Triadimefon	No	Orchard scenario exceeds COC at 80 acre field size only.
Triallate	No	Soil scenario exceeds COC at all field sizes.
Triclopyr, salts and esters	No	Row scenario exceeds COC at 80 acre field sizes and larger.
Triflumizole	No	Cole scenario exceeds COC at 40 acre field sizes and larger.
Trifluralin	Yes	Soil scenario exceeds COC at 20 acres and larger.

Section 5.0: Registration Review Chemical Volatilization Screen Characterization

There are a number of considerations and uncertainties that should be taken into account in the interpretation of the results of the Registration Review chemical volatilization screening analysis presented in Section 4. The Agency acknowledges that there are uncertainties associated with the current knowledge base relating to the processes that govern volatilization of conventional pesticides from soil and foliar surfaces. However, the Agency is confident that the screening analysis uses data and methodologies that results in a consistent and health protective framework to assess whether a pesticide does not pose potential inhalation bystander risks resulting from volatilization of conventional pesticides.

Some of the considerations and uncertainties that should be considered in the interpretation of the screening analysis results include the following:

Modified Woodrow Equation Characterization

- Use of the modified Woodrow equation to predict flux from soil and foliar surfaces is consistent with the recommendations of the December 2009 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) meeting entitled "Scientific Issues Associated with Field Volatilization of Conventional Pesticides"[21]. In order to be more health protective, the Agency used the data provided in the Woodrow paper to estimate the 90% upper confidence limit around the slope and intercept so that 90% of the estimated flux rates would exceed the measured values. In addition, as more volatilization data for other chemicals become available it may be possible to update this equation.
- It is important to note that the Agency used physical/chemical properties for the active ingredient, or technical chemical, and these may not reflect the physical/chemical properties of the end-use product(s). Most pesticides are mixed or diluted with water, solvents, and inerts. The addition of these components can impact these physical/chemical properties relative to the active ingredient in its technical form.

AERSCREEN Characterization

- AERSCREEN generates a maximum one-hour air concentration assuming air flow remains constant and in a single direction. The values reported in the tool are worst case values and should be characterized as such (Appendix A).
- AERSCREEN models air flow for simple, uniform terrain. Because of the complex topography and air flow patterns in an orchard, use of the results generated for orchards should be characterized appropriately.[22] While the topography for cole or row crops is not completely uniform, it is believed that the differences are not significant enough to impact the air flow regime and concentrations outside the treated field.

[21] http://www.regulations.gov/ (EPA-HQ-OPP-2009-0687)

[22] Unlike AERSCREEN, (interactive mode), the refined model AERMOD considers flow around or above complex mountainous terrain. However, neither AERSCREEN nor AERMOD considers complex flow patterns through highly localized non-homogeneous surfaces such as orchard groves.

- For simplicity, the fields in AERSCREEN were modeled as squares and the modeled field sizes were limited. While this may not necessarily reflect all real-world agricultural scenarios, it is consistent with current Agency fumigant assessment methodology.
- In most cases, the maximum AERSCREEN concentration at any distance corresponded to the minimum wind speed of 0.5 m/s. In the case of many, but not all, conventional pesticides, the maximum flux rate is likely to occur during the middle of the day when temperatures are highest and air turbulence and wind speed have increased. As a result, for conventional pesticides, matching the maximum flux rate with the minimum wind speed will result in conservative, health protective air concentrations around a treated field.
- Users need appropriate justification for selecting field sizes and crop scenarios used in the modeling runs. Any differences between what was modeled and what is expected to occur in the real world should be characterized.
- Although the Agency chose to use spring as the default application timing for the Registration Review chemical screening analysis, if a particular pesticide has a very specific application timing requirement on the label, use of another season may be more appropriate and result in a different outcome.

Hazard Characterization

- The Volatilization Screening Tool provides risk estimates for exposure to chemicals in the vapor phase; however, even for those chemicals that have route-specific inhalation toxicological data, these studies are typically not performed under vapor phase conditions. The majority of these data are performed with aerosols, and following Agency guidelines, the particles are typically 2-4 µm in size. Vapors and particles have the potential to be different in terms of the site of deposition, absorption, dose, and toxicity. At the 2009 Volatilization SAP, one of the questions asked by the Agency of the Panel related to the difference in toxicity between vapors and aerosols; however, the Panel knew of no studies that have investigated the health impact of exposure to a single chemical using different phases (e.g., vapors and aerosols). Since that time, data conducted using chlorpyrifos indicate that aerosols may be more toxic than vapors, at least for this specific chemical. More inhalation toxicological data, including direct comparison vapor/aerosol studies, are needed to further elucidate this issue.