AGENDA

FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN MEETING

December 1 – 3, 2009

FIFRA SAP WEB SITE http://www.epa.gov/scipoly/sap/
OPP Docket Telephone: 703-305-5805
Docket Number: EPA-HQ-OPP-2009-0687

U.S. Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard South Bldg.
2777 S. Crystal Drive, Arlington, VA 22202

Scientific Issues Associated with Field Volatilization of Conventional Pesticides

Please note that all times are approximate.
See note at the end of the Agenda.

Tuesday, December 1, 2009

9:00 A.M.	**Opening of Meeting and Administrative Procedures by Designated Federal Official –** Sharlene Matten, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA
9:05 A.M.	**Introduction and Identification of Panel Members –** Kenneth Portier, Ph.D., Session Chair, FIFRA Scientific Advisory Panel
9:15 A.M.	**Welcome and Opening Remarks –** Steven Bradbury, Ph.D., Deputy Director, Office of Pesticide Programs, EPA
9:25 A.M.	**Goals and Objectives –** Tina Levine, Ph.D., Director, Health Effects Division, Office of Pesticide Programs, EPA
9:35 A.M	**Introduction: Assessment of Semi-Volatile Pesticides –** Jeff Evans, Health Effects Division, Office of Pesticide Programs, EPA
10:10 A.M.	**BREAK**
10:25 A.M.	**Overview of Available Pesticide Air Monitoring Data –** Charles Smith, Health Effects Division, Office of Pesticide Programs, EPA
11:10 A.M.	**Exposure Estimation for Semi-Volatile Pesticides –** Faruque Khan, Ph.D., Chuck Peck, Gabe Rothman, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
12:15 P.M.	**LUNCH**
1:30 P.M.	**Introduction: Hazard Assessment of Semi-Volatile Pesticides –** Judy Facey, Ph.D., Health Effects Division, Office of Pesticide Programs, EPA
2:00 P.M.	**Overview of Reference Concentration (RfC) Methodology –** Annie Jarabek, Ph.D., National Center for Environmental Assessment, Office of Research and Development, EPA
3:00 P.M.	**BREAK**
3:15 P.M.	**Hazard Assessment of Semi-Volatile Pesticides –** Elizabeth Mendez, Ph.D., Health Effects Division, Office of Research and Development, EPA
4:15 P.M.	**Risk Assessment of Semi-Volatile Pesticides –** Charles Smith, Health Effects Division, Office of Pesticide Programs, EPA
5:30 P.M.	**Adjourn**

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Wednesday, December 2, 2009

9:00 A.M. **Opening of Meeting - Administrative Procedures by Designated Federal Official** - Sharlene Matten, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA
9:05 A.M. **Introduction and Identification of Panel Members –** Kenneth Portier, Ph.D., Session Chair, FIFRA Scientific Advisory Panel
9:10 A.M. **Follow-up from Previous Day's Discussion –** TBD, Health Effects Division, Office of Pesticide Programs, EPA
9:30 A.M. **Public Comments**
10:30 A.M. **BREAK**
10:45 A.M. **Public Comments cont'd**
12:00 P.M. **LUNCH**
1:00 P.M. **Charge to the Panel –** ***TOPIC A: Exposure Assessment Issue***

Traditionally, the Agency's assessment of bystander inhalation exposure to volatile pesticides has relied extensively on the use of air monitoring data. However, for the fumigants, an exposure assessment methodology was developed that combined the use of air models and air monitoring data. The Agency has taken the exposure assessment methodologies developed for the fumigants and further adapted them by utilizing soil models to predict field volatilization of conventional pesticides from plant and soil surfaces. Based on this premise, the Agency has identified several key factors for consideration by the Panel. They include the evaluation of the approaches and data sources used in the tiered exposure estimation methodology and use of soil models for predicting flux of conventional pesticides. Specifically, the Agency identified the following issues for the Panel to consider:

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1. Tier I Approach for Identifying Volatile Chemicals of Concern for Risk Assessment, Air Concentration. The Tier I approach incorporates the use of vapor pressure alone to arrive at a saturated concentration in air. The estimated air concentration can be compared with available toxicity data to evaluate inhalation exposure concerns to human and other terrestrial organisms.

   Please comment on the Agency's approach for using the Tier I air concentration estimation method as a screening procedure. Please discuss the strengths and limitations of the screening approach. Please identify any alternative methods and/or physical-chemical properties, if any, which may be utilized as a screening procedure to identify chemicals with potential inhalation exposure concerns.

2. Tier II Approach for Identifying Volatile Chemicals of Concern for Risk Assessment, Volatility and Flux Models. Two options are being considered to refine the Tier I estimation method. Option A incorporates the use of physical-chemical properties including application rate, vapor pressure, solubility, and K_{oc} in an empirically-derived function to estimate flux rates. This option has fewer constraints and requires fewer input parameters to generate flux rates as compared to Option B described below.

   a. *Given the state of the science, please comment on the applicability of using the Option A model to predict flux rates. Please discuss the strengths and limitations of this approach and how these impact the results. Please identify alternative methods, if any, which may be utilized to identify chemicals with potential inhalation exposure concerns.*

   Tier II, Option B is a refined process which utilizes fate and transport models to predict flux rates of applied pesticides which off-gas from treated fields. Optimum fate and transport models consider mechanisms related to volatilization, biodegradation, abiotic degradation, physical-chemical properties, runoff, crop uptake, and leaching to account for the transformation and movement of the entire initially applied material. Volatilization mechanisms from bare soil and crop canopy surfaces are also important processes which the Agency believes ought to be considered to fully account for volatilization and diffusion from the vadose zone and canopy into the atmosphere. The Agency has utilized two models, the Pesticide Root Zone Model (PRZM) and the Pesticide Emission Assessment at Regional and Local Scales (PEARL) which incorporate these mechanisms and have the utility for the prediction of flux rates from treated fields. Option B requires extensive knowledge on environmental fate properties, as well as information related to application site, crop management and meteorology.

   b. *Please comment on the applicability of using fate and transport models to predict flux rates given the state of the science. Please discuss the strengths*

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and limitations of both models and how these impact the results. Please identify any fate and transport model(s) which the Agency has not considered in this analysis which would be applicable for pesticide applications and crop management scenarios.

3:00 P.M. BREAK

3:15 P.M. Charge to the Panel – *TOPIC B: Toxicological Assessment Issues*

As the Agency's understanding of the state-of-the-science in inhalation toxicology has evolved so has the Agency's approach to conducting inhalation hazard and risk assessments. This evolution has seen the Agency move from converting oral doses to inhalation concentrations to using the RfC methodology and/or physiologically-based pharmacokinetic (PBPK) models. As OPP continues to work on refining the risk assessment paradigm, the Agency is seeking the SAP's input on a number of key factors. They include the use of oral toxicity studies when inhalation studies are not available and the use of aerosol inhalation toxicity studies to represent toxicity to vapors of the same chemical. Specifically, the Agency identified the following issues for the Panel to consider:

1. The analysis conducted by the Agency indicates that, in general, oral toxicity studies may not accurately represent the full spectrum of toxic effects that may occur as a result of inhalation exposure. The analysis also indicates that unless the same endpoints are identified through both routes of exposure, oral toxicity studies frequently underestimate toxicity by the inhalation route. The Agency has not been able to discern any patterns in this under/over estimation. *Please comment on any potential patterns that the Agency has not identified.*

2. For a significant number of conventional pesticides, inhalation toxicity studies are not available. *Please comment on the scientific strengths and weaknesses of available approaches that may be used in the interim to assess inhalation hazard in the absence of inhalation toxicity studies.*

3. For inhalation toxicity studies the test material is typically aerosolized. After volatilization, however, the Agency anticipates exposures to vapors rather than the aerosolized particles. *Please comment on the predictive capabilities of aerosol studies to identify potential toxic effects and/or quantify the dose-response resulting from exposure to vapors. Is the Panel aware of any studies that quantitatively compare inhalation toxicity after exposure to vapors and aerosols? In the absence of such data, can the Panel recommend an approach to account for the potential differences between vapors and aerosols?*

5:30 P.M. Adjourn

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Thursday, December 3, 2009

9:00 A.M. **Opening of Meeting - Administrative Procedures by Designated Federal Official –** Sharlene Matten, Ph.D., Designated Federal Official, Office of Science Coordination and Policy, EPA

9:05 A.M. **Introduction and Identification of Panel Members –** Kenneth Portier, Ph.D., Session Chair, FIFRA Scientific Advisory Panel

9:10 A.M. **Follow-up from Previous Day's Discussion –** TBD, Health Effects Division, Office of Pesticide Programs, EPA

9:40 A.M. **Charge to the Panel –** ***TOPIC C: Risk Assessment Issues***

The Agency discussed its methodology for combining the exposure estimation methodologies and inhalation toxicological approaches to estimate post application bystander inhalation risks resulting from field volatilization of conventional pesticides. In estimating post application bystander inhalation risks, there a few principles that should be followed: (1) It is important to properly match the duration of the exposure with a proper toxicity study of comparable duration. (2) Both dissipation of air concentrations around a treated field as well as when retreatment of the field may occur need to be considered. (3) Clearly define the uncertainties and limitations of this type of assessment. The Agency has identified the following issues for the Panel to consider with respect to estimating post application bystander inhalation risks:

Please comment on the strengths and limitations of the Agency's use of the empirical and modeled air concentrations in the provided risk assessment case study. Does the Panel agree that the post application bystander inhalation risk

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estimate case study appropriately matches the duration of the exposure with the proper toxicological study of the same duration? Please comment on the scientific strengths and weaknesses of conclusions and characterization regarding the estimated risks presented in the case study.

10:30A.M. BREAK
10:45 A.M. Charge to Panel –Discussion cont'd (as needed)
12:00 P.M. Adjourn

Please be advised that agenda times are approximate; when the discussion for one topic is completed, discussions for the next topic will begin. For further information, please contact the Designated Federal Official for this meeting, Dr. Sharlene Matten, via telephone: 202-564-0130; fax: 202-564-8382; or email: matten.sharlene@epa.gov.