

**FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN MEETING
JANUARY 9 - 12, 2007
FIFRA SAP WEB SITE <http://www.epa.gov/scipoly/sap/>
OPP Docket Telephone: (703) 305-5805
Docket No.: EPA-HQ-OPP-2006-0856**

**TUESDAY, JANUARY 9, 2007
U.S. Environmental Protection Agency, One Potomac Yard, South Building
Conference Center, Lobby Level
2777 S. Crystal Drive, Arlington, Virginia 22202**

REVIEW OF WORKER EXPOSURE ASSESSMENT METHODS

- 8:30 a.m. Introduction and Identification of Panel Members** – Steven Heeringa, Ph.D., FIFRA SAP Chair
- 8:40 a.m. Administrative Procedures by Designated Federal Official** – Myrta R. Christian
- 8:45 a.m. Opening Remarks** – Tina Levine, Ph.D., Director, Health Effects Division, Office of Pesticide Programs, EPA
- 8:55 a.m. Introduction and Overview** – Jeff Evans, Health Effects Division, Office of Pesticide Programs, EPA
- 9:20 a.m. Historical Perspective** – John Worgan, Health Canada, Pest Management Regulatory Agency
- 10:00 a.m. BREAK**
- 10:15 a.m. Case Study** – Jeff Dawson, Health Effects Division, Office of Pesticide Programs, EPA
- 11:45 a.m. Issues Related to Antimicrobial Pesticides** – Cassi Walls, Ph.D., Antimicrobial Division, Office of Pesticide Programs, EPA
- 12:00 noon LUNCH**
- 1:00 p.m. AHETF Overview and Approach** – AHETF Representatives Richard H. Collier, Ph.D., Victor Canez, Ph.D., and Curt Lunchick
- 2:40 p.m. AEATF Overview and Approach** – AEATF Representative Ryan Williams, Ph.D.
- 3:00 p.m. BREAK**
- 3:15 p.m. Public comments**
- 5:00 p.m. ADJOURNMENT**

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**WEDNESDAY, JANUARY 10, 2007
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REVIEW OF WORKER EXPOSURE ASSESSMENT METHODS

- 8:30 a.m.** **Introduction and Identification of Panel Members** – Steven Heeringa, Ph.D.,
FIFRA SAP Chair
- 8:35 a.m.** **Administrative Procedures by Designated Federal Official** – Myrta R.
Christian
- 8:40 a.m.** **Follow-up from Previous Day’s Discussion** – Jeff Dawson, Jeff Evans, Health
Effects Division, Office of Pesticide Programs, EPA
- 9:00 a.m.** **Agency – Biological Monitoring/Passive Dosimetry Comparison** – Sheryl
Beauvais Ph.D., California EPA, Department of Pesticide Regulation
- 9:45 a.m.** **Agency Methods for Measuring Hand Exposure** – Jeff Dawson, Jeff Evans,
Health Effects Division, Office of Pesticide Programs, EPA
- 10:15 a.m.** **BREAK**
- 10:30 a.m.** **AHETF Comparison of Passive Dosimetry and Biological Monitoring** –
AHETF Representatives John Ross, Ph.D. Graham Chester, Doug Baugher,
Ph.D., Bruce Houtman and Curt Lunchick
- 12:00 noon** **LUNCH**
- 1:00 p.m.** **Questions to the Panel**

1) Data Needs

EPA believes that many studies within our current database have limitations. In some cases, the Agency is lacking data to address modern pesticide application equipment and techniques. EPA believes that additional data could significantly improve our ability to estimate and better characterize the range of worker exposure with greater certainty.

Please comment on these limitations and EPA’s conclusion that additional data could improve significantly the Agency’s ability to assess worker exposure. Also, please comment on the selection criteria proposed by the AHETF and AEATF in their respective submissions for evaluating the extent to which existing data would meet EPA’s exposure assessment needs.

- 2:30 p.m.** **BREAK**
- 2:45 p.m.** **Panel Discussion (continued)**

2) Passive Dosimetry Performance

The common approach for conducting dermal exposure monitoring studies relies on the use of whole-body dosimetry, handwashing, and facial/neck wipes. In some cases, biological monitoring is also used as an alternative method. Exposure estimates in Agency risk assessments, however, typically rely on “to the skin” measurements (i.e., potential dose) coupled with dermal absorption data or dermal toxicity studies in order to calculate risks. The Agency believes that these methods are complementary and that they can provide appropriate estimates for exposure assessment but that the results directly relate to the reliability of the inputs used. Please comment on the Agency’s conclusion regarding passive dosimetry and biological monitoring, including whether a systematic bias exists in either approach.

Based on the information presented, the Agency has particular concerns over three specific aspects of how these studies are conducted including (1) the possible need to correct for the efficiency of the handwashing technique; (2) compensating for absorption of residues through the skin during sample collection periods; and (3) the breakthrough of residues under whole-body dosimeter garments. Please comment on the need to systematically account for residue losses due to these potential method biases. If there is a need, please describe how these corrections should be accomplished in a way that could reduce uncertainties in the resulting exposure estimates.

4:15 p.m. Panel Discussion (continued)

3) Passive Dosimetry vs. Biomonitoring

EPA believes that a comparison of exposure estimates derived from data collected through biomonitoring with data collected through passive dosimetry is the most appropriate way to assess the predictive nature of a passive dosimetry-based approach for estimating worker exposure. Please comment on the strengths and limitations of this kind of comparison for judging the potential utility of passive dosimetry data in conducting exposure assessments.

EPA has conducted such a comparison using available data and believes that the comparison shows sufficient concordance of estimates based on biomonitoring data and passive dosimetry data to support the conclusion that a passive dosimetry-based approach can generate data that can be used to develop relatively predictive estimates of worker exposure for a wide variety of scenarios and activities. Please comment on the adequacy of the analysis to support EPA’s conclusion.

5:30 p.m. ADJOURNMENT

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**THURSDAY, JANUARY 11, 2007
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REVIEW OF WORKER EXPOSURE ASSESSMENT METHODS

- 8:30 a.m.** **Introduction and Identification of Panel Members** – Steven Heeringa, Ph.D.,
FIFRA SAP Chair
- 8:35 a.m.** **Follow-up from Previous Day’s Discussion** – Jeff Dawson, Jeff Evans, Health
Effects Division, Office of Pesticide Programs, EPA
- 8:50 a.m.** **Proportionality Between Exposure and Amount of Active Ingredient
Handled** – Matthew Crowley, David J. Miller, Health Effects Division, Office of
Pesticide Programs, EPA
- 10:00 a.m.** **BREAK**
- 10:15 a.m.** **Statistical Basis for AHETF Data Development Program** – AHETF
representatives Bryce Landenberger, Curt Lunchick and Larry Holden, Ph.D.
- 12:00 noon** **LUNCH**
- 1:00 p.m.** **Questions to the Panel**

4) Normalization of Exposure by Amount of Active Ingredient Handled (AaiH)

The normalization of exposure by AaiH – the unit exposure – has, since the mid-1980s, been the principle relationship underlying the use of exposure data in the Agency's pesticide handler exposure assessments. It is based on the assumption that the two variables are proportional. That is, if one doubles the amount of pesticide they handled or applied, the resultant exposure will be doubled as well.

The Agency is unsure whether the results of our exploratory work showing that proportionality between exposure and AaiH is reasonable in some but not all cases, is a function of limitations of the data within PHED or whether this relationship is in fact not a reasonable assumption for all scenarios. It may be the case that an additional ancillary variable (e.g., boom length, # of tank mixes, or # de-couplings in a closed loading system), in addition to or in place of AaiH, may improve the predictive capabilities of our exposure model.

Though it is recognized that neither the studies in our current database nor the proposed studies by the AHETF were designed for the primary purpose of examining proportionality between exposure and AaiH or to determine the extent to which other parameters influence exposure, compared with our current database, the Agency believes that the proposed AHETF studies will generate data that will reinforce the assumption of proportionality

between exposure and AaiH or, alternatively, inform the applicability of another variable as a more appropriate predictor of exposure.

Based on the themes presented on this topic including its historical precedent, its application in risk assessment and subsequent risk management decisions, the Agency's exploratory work using the six PHED scenarios in the case study, and the study design and objectives of the AHETF, please comment on the assumption of proportionality between exposure and AaiH, as a default. Also, please provide comments on whether the proposed AHETF study design is adequate to evaluate proportionality between exposure and AaiH? What other parameters should AHETF study designs measure in order to improve the prediction capabilities of our exposure model?

2:30 p.m. BREAK

2:45 p.m. Panel Discussion (continued)

5) Within-worker and Between-worker Variability

The proposed AHETF study design does not include true worker replicates and is not intended to examine the issue of variability within workers. The AHETF notes that to appropriately investigate this issue would require significantly more sampling and resources. They propose, however, that their single-day exposure distribution results can be used to evaluate longer term multiple day exposures by placing reasonable limits on expected intra-class correlation coefficients (ICC): they indicate that, from their own research and review of the literature, the ICC is likely to be between 0.3 and 0.5 over relatively short periods of time (e.g., seasonal), and likely to be even lower over longer periods of time.

Please comment on the AHETF's approach to estimating the number of samples (MU) needed to determine within worker variability and their conclusion on the importance of measuring such variability in their proposed studies.

4:15 p.m. Defining the Scope of a Research Plan Designed to Quantify Occupational Handler Exposures – David J Miller, Jeff Evans, Health Effects Division, Office of Pesticide Programs, EPA

5:30 p.m. ADJOURNMENT

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- 8:35 a.m.** **Follow-up from Previous Day’s Discussion** – Matthew Crowley, David J
Miller, Health Effects Division, Office of Pesticide Programs, EPA
- 8:50 a.m.** **AHETF Research Plan Development and Considerations** – AHETF
representatives Victor Canez, Ph.D., Richard Collier, Ph.D., Bruce Houtman,
Curt Lunchick and Larry Holden, Ph.D.
- 10:00 a.m.** **BREAK**
- 10:15 a.m.** **Questions to the Panel**

6) Sample Size: Number of Sites and Subjects per Scenario/Activity

The Agency’s goal is to ensure that monitoring studies rely on sample sizes that adequately represent the range of exposure of people who engage in a particular handler scenario and activity. It is also recognized that occupational monitoring studies are costly and have many logistical obstacles. The Agency is also concerned about limiting the numbers of participants in these types of studies in accordance with the ethical requirements described in Subpart K (40CFR26) and the recent criteria outlined by the Agency’s Human Studies Review Board. The Agency’s current guidelines recommend 15 monitoring units for each scenario. In addition, the AHETF has provided a rationale for the number of samples in their study design.

Please comment on the uncertainties associated with the Agency’s and AHETF’s recommended number of monitoring units. In your comments, please include any recommendations you may have regarding specific statistical analyses that may assist the Agency in developing better understanding of these uncertainties and characterizing them in a complete and transparent manner in Agency assessments based on these data.

12:00 noon ADJOURNMENT

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, Ms. Myrta Christian, via telephone: (202) 564-8450; fax: (202) 564-8382; or email: christian.myrta@epa.gov