



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

Office of  
Prevention, Pesticides and  
Toxic Substances

**DATE:** July 11, 2007

**MEMORANDUM**

**Subject:** Transmission of Background Materials for the August 14-15, 2007 FIFRA Scientific Advisory Panel Entitled "Review of EPA/ORD/NERL's SHEDS-Multimedia Model, Aggregate Version 3"

**To:** Melissa Kramer, Designated Federal Official  
FIFRA SAP  
Office of Science Coordination and Policy

**From:** Dana Vogel  
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Health Effects Division (7509PY)

**Through:** Tina Levine, Ph.D., Director  
Office of Pesticide Programs  
Health Effects Division (7509PY)

Attached please find the first set of background materials (1 of 2) and related charge questions for the August 14-15, 2007 FIFRA Scientific Advisory Panel entitled "Review of EPA/ORD/NERL's SHEDS-Multimedia Model, Aggregate Version 3." The purpose of this 2-day meeting is to request:

- (1) a formal model review by the SAP on the Stochastic Human Exposure and Dose Simulation for Multimedia, Multipathway Pollutants (SHEDS-Multimedia), aggregate version 3 (residential module);
- (2) a peer consultation by the SAP on planned methodologies to extend SHEDS-Multimedia version 3 to version 4; and
- (3) a peer consultation by the SAP on the SHEDS-Multimedia dietary module that will also be incorporated into SHEDS-Multimedia version 4.

This SAP review is part of the Agency's ongoing process to enhance probabilistic risk assessments and OPP's ongoing efforts to address safety standards of the Food Quality Protection Act (FQPA) of 1996. FQPA amended the laws under which EPA evaluates the safety of pesticide residues in food. Section 408(b)(2)(D)(v) and (vi) of the Federal Food Drug and Cosmetic Act, as amended by FQPA, specifies that when determining the

safety of a pesticide chemical, EPA shall consider aggregate exposure (i.e., total dietary (food and water), residential, and other non-occupational) and available information concerning the cumulative effects to human health that may result from exposure to other substances that have a common mechanism of toxicity.

SHEDS-Multimedia can address many useful aspects of aggregate and cumulative risk assessment related to population aggregate exposures for different multimedia chemicals and the important contributing pathways and factors. Such information will be useful in identifying populations and exposure scenarios of greatest concern for this class of chemicals. These populations and exposure scenarios will in turn be used to determine the most relevant chemical/pyrethroid combinations for which hazard/exposure factors information will need further development in order to support a PBPK dose modeling approach. EPA plans to extend the current single chemical aggregate version (version 3) of SHEDS to version 4, a cumulative (multi-chemical) version that will include both the residential and dietary modules, i.e., estimate both residential and dietary exposures for simulated individuals. The cumulative version of SHEDS, which will also include enhancements to version 3 to be reviewed by the August 14-14, 2007 SAP, will be used to estimate cumulative exposure to pyrethroid pesticides. Agency staff from ORD/ NERL are collaborating with the Office of Pesticide Programs (OPP) on development and application of the various modules for the SHEDS-Multimedia version 4 model.

To assist the August 14-15, 2007 FIFRA SAP in their review of the SHEDS-Multimedia version 3 (aggregate residential) model, each FIFRA SAP member will be provided CD(s) containing a technical report describing the SHEDS-Multimedia version 3 model, annotated SHEDS code with a graphical user interface, and a user guide for the graphical user interface. Below are the related charge questions for this portion of the SAP meeting. Three issues will be presented for the FIFRA SAP review of the SHEDS-Multimedia version 3. The materials and related charge questions for Issue 1 are detailed below. Separate materials and charge questions will be provided subsequently to the SAP for Issue 2 (version 4 planned methodologies) and Issue 3 (SHEDS-dietary module).

#### **I. Charge Questions Related to the Review of EPA/ORD/NERL's SHEDS-Multimedia Model, Aggregate Version 3**

##### ***Issue 1: Documentation, completeness, and clarity of the technical aspects and usability of the SHEDS-Multimedia version 3 (aggregate residential) model***

**Question 1:** The SHEDS-Multimedia version 3 User's Manual provided to the SAP presents installation and operational instructions for the software.

- a) Were Panel members able to load the software on to their computers? What, if any, difficulties were encountered in loading or running the software?
- b) The SHEDS-Multimedia version 3 graphical user interface (GUI) was designed to be user-friendly to exposure modelers and risk assessors. Please comment on the

organization and usability of the GUI, any difficulties you encountered, which features and output capabilities were most useful, and whether any additional options would be helpful. Please also comment or offer suggestions for improving the GUI/model interface.

- c) Please comment on the organization, clarity, completeness, and usefulness of the User Guide document and provide any suggestions for improvement.

**Question 2:** The SHEDS-Multimedia version 3 Technical Manual provided to the SAP provides an overview of the SHEDS-Multimedia aggregate residential model; presents detailed descriptions of key model components; and describes the model construct and algorithms, required inputs, and analysis/output capabilities.

- a) Please comment on whether the descriptions of specific model components are scientifically sound and whether the algorithms described in the Technical Manual represent the state of the science for performing exposure assessments. Please also comment or offer suggestions for improving or modifying these algorithms or other aspects of the model construct.
- b) Please comment on the organization, clarity, completeness and usefulness of the Technical Manual and provide any suggestions for improvement.

**Question 3:** The Source Code Directory on the CD provided to the SAP includes annotated code for the exposure algorithms used in the SHEDS-Multimedia aggregate residential model.

- a) Please comment on whether the annotated code is sufficiently clear such that the algorithms can be followed and understood.
- b) Please also comment on whether these algorithms are technically correct and consistent with the descriptions provided in the technical manual.

## **II. List of Attachments for SHEDS-Multimedia version 3 Residential Module Review:**

1. Installation Instructions for the SHEDS-Multimedia version 3 (aggregate residential) model (filename: SHEDS\_Multimedia\_Installation.doc)
2. SHEDS-Multimedia version 3 (aggregate residential) model (installation for code review and running/testing model with graphic user interface)( filename: SHEDS\_Multimedia\_Setup\_3.14c.exe)
3. SHEDS-Multimedia version 3 (aggregate residential) model Users Guide (filename: SHEDS-Multimedia3\_UsersGuide\_06\_13.pdf)
4. SHEDS-Multimedia version 3 Technical Manual (filename: SHEDS\_TechManual\_06-14.pdf)