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

Office of
Prevention, Pesticides and
Toxic Substances

DATE: July 26, 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". **PART 3 of 3.**

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

From: Steven M. Nako
Office of Pesticide Programs
Health Effects Division (7509PY)

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

Attached please find the third set of background materials (3 of 3) 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. This transmittal memo pertains only to ***Issue 3: An Update on the Development of the SHEDS-Dietary Model.***

Three issues will be presented for the FIFRA SAP. The materials and related charge questions for Issue 3 are detailed below.

Issue 3: An Update on the Development of the SHEDS-Dietary Model

I. Charge Questions

Question 1. Eating Occasion Analyses.
As described in the SHEDS dietary background document, the timing information available in CSFII can be used to model food and indirect water intake throughout the day. With the ability to incorporate the timing of eating occasions in dietary exposure assessments, it is possible to assign either the same residue or a different residue to foods consumed on multiple eating occasions. In certain instances, the former seems logical (e.g, consumption of leftovers) while in other instances the latter appears appropriate (e.g, hash browns at home for breakfast and fried potatoes away from home for dinner).

- Please comment on developing simple decision rules - as described in the document - for assigning residues to commodities eaten on multple eating occasions.

Question 2. Longitudinal Dietary Consumption
To estimate exposures associated with longer time periods than 1 day, SHEDS-Dietary draws from diary pools based on gender, age group, season and day-type (weekday, weekend). The 8-diary approach of SHEDS described in the background document limits each individual's diet to 2 per season, one of which corresponds to a weekday and the other corresponds to a weekend day.

- Please comment on the 8-record approach in SHEDS-dietary and the selection of age group, gender, season and day-type from which to create the "diary pools". What other approaches does the Panel recommend? Can the Panel suggest any "bounding approaches" that may - based on knowledge of actual eating patterns - provide upper and lower limits for longitudinal exposure estimates (e.g., yearlong consumption of the same diary throughout the year vs. random daily selection of CSFII diaries).

Question 3. Bayer Drinking Water Consumption Survey Data

The CSFII data does not contain information on the time and amounts of direct drinking water consumption. Bayer CropScience sponsored a study, Drinking Water Consumption Survey (DWCS) that was designed to obtain a distribution of water intake for a 24-hour time period from a representative sample of the US population. Participants recorded their water consumption (time of day and amount consumed) over a one-week (7 consecutive day) period. The authors, Barraj *et.al.* (2004) suggested that it may be possible to "allocate the total daily water consumption amount reported in the CSFII into various drinking occasions" using information from the DWCS. In addition to offering a fixed option for allocating direct drinking water throughout the day, the Agency is planning to include in SHEDS-Multimedia v. 4 the option to allocate direct drinking water consumption throughout the day through empirical use of the Bayer DWCS data.

- Please comment on the advantages and disadvantages of providing an option to use the Bayer DWCS data in SHEDS-Multimedia v. 4. Please include in your comments any statistical concerns or issues associated with the design and conduct of the DWCS study.

Question 4. Bootstrap Approach to Uncertainty Analysis

Sensitivity and contribution analyses are a routine part of OPP risk assessments. These analyses help inform the risk manager how exposures may change when certain model inputs are modified. These modifications to the model inputs are typically performed "one at a time" to permit isolation of the effect. In a typical risk assessment, all the dietary consumption data (*i.e.*, reported CSFII diaries) are used along with the best available pesticide residue data. OPP risk assessors specify a sufficiently large number of Monte-Carlo iterations such that exposure estimates are stable with respect to the random seed.

The Agency has not conducted formal quantitative uncertainty analyses. The Agency presented a simple bootstrapping procedure for conducting uncertainty analyses, utilizing only a subset of the consumption and residue data inputs. That procedure was designed to provide some insight into the question 'How much better would our exposure estimates be if we had more data' by conducting the uncertainty analysis in the other direction.

- Please comment on the scientific soundness and utility of the proposed bootstrap uncertainty approach.
- Can the Panel recommend alternative approaches - and how they might be interpreted and used - for conducting uncertainty analyses of dietary exposure estimates?

Question 5. NHANES Dietary Consumption Survey
The SHEDS-Dietary paper noted that the NHANES 1999-2006 dietary consumption data does not contain information on season nor region.

- Please suggest statistical or other methods that might be used to determine the extent to which region- and season- specific dietary consumption amounts and patterns might be important in developing dietary exposure estimates. Please consider in your response whether and how quantitative uncertainty methods could be used in addressing this issue.

II. Attachments for SHEDS-Dietary Update:

1. An Update on the Development of the SHEDS-Dietary Model