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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 9, 2001

MEMORANDUM

Subject: Transmission of Material for FIFRA Scientific Advisory Panel, Session:

LifeLineTM - System Operation Review

To: Olga Odiott, Designated Federal Official

FIFRA SAP

Office of Science Coordination and Policy (7101C)

From: Francis Suhre, Senior Scientist

Office of Pesticide Programs Health Effects Division (7509C)

Accompanying this memorandum are documents applicable to the FIFRA SAP Session: LifeLineTM - System Operation Review, they are:

- Overview of the Fundamentals of LifeLineTM Version 1.0
- Annotated code of algorithms used in LifeLineTM Version 1.0
- Questions to SAP

In addition, Hampshire Research Institute and The LifeLine Group, Inc. will provide each Panel member a copy of the LifeLineTM - CD containing:

- Model Software
- Users' Manual
- Technical Manual
- Demonstration Case
- Knowledge Base files.

LifeLineTM Version 1.0 was developed under a cooperative agreement between US EPA and HRI. You will be receiving a copy of the complete Version 1.0 software under separate cover. The software and attendant documentation and other relevant information will be on a disc that

Transmittal Memo LifeLine™ System Operation Review March 2001, FIFRA SAP has been coded for your personal use for official SAP business. It will be sent to you by The LifeLine Group along with instructions for loading it onto your computer. EPA is providing the program for your exclusive use in SAP business as part of the software's use for official Federal Purposes. EPA recognizes that this software is copyrighted by The LifeLine Group, as is the standard practice for work created under cooperative agreements. As official agents of the government, you too are expected to abide by the copyright provisions The Panel is urged to explore the software and its attendant documentation in preparation for the SAP meeting where LifeLine(tm) will be discussed. If you have any questions or problems, you may contact F. Bart Suhre (703-305-6878) for assistance, or you may contact a representative of The LifeLine Group for assistance. Their contact information will be provided with the software.

Background: Passage of the Food Quality Protection Act in August of 1996 necessitated significant revisions to EPA risk assessment policies, guidance documents and associated models for estimating exposure and risk to pesticides. Access to more sophisticated models is vital to the implementation of FQPA and for a better understanding of the potential for exposure and the related risk from pesticide use.

LifeLineTM is a model for assessing aggregate and cumulative exposure and risk to pesticides. Previous SAP presentations for LifeLineTM focused on model design (Sept. 1999) and model utility (Sept. 2000). This presentation (March 2001) will focus on the operating system and will solicit SAP comments and advice with respect to understanding and operating the LifeLineTM model

Using the model: The LifeLine[™] Software is a sophisticated model, with multiple assessment and reporting options. It contains relatively complex analysis operations for routes of exposure and uses many different databases and exposure assumptions. Becoming familiar with all aspects of the software will require an investment of time and intellectual energy.

To assist with the understanding of the model, the software CD contains a Users' Manual. To assist in learning the system operations, the software CD also contains a Demonstration Case. The Demonstration Case walks a new software user through the various program modules, demonstrates various forms of data entry, editing of data and selection of analysis options. It requires 8-16 hours to complete the entire Demonstration Case. Using the Demonstration Case provides a number of options to investigate how data are entered into Lifeline and to create reports of analysis results. These ways differ in the level of effort requested of the model user. The most straightforward and least time consuming method to investigate data inputs and analysis results is to go immediately to the Lifeline Model and the Risk-Dose-Exposure Reports, by-passing the modules to enter or edit model inputs. The user will be prompted to select certain input files, an .rkg file, a .res file, and a .twc file (consult Users Manual for descriptions of these

Transmittal Memo LifeLine™ System Operation Review March 2001, FIFRA SAP files). These files in addition to other information the user will be asked to provide will be used to create a hypothetical population. Pre-made .rkg, .res, and .twc files are provided on the Lifeline CD-Rom. These files can be used to investigate the Lifeline Model and the Risk-Dose-Exposure Reports options, without entering or exploring information through the accompanying modules. This approach would allow quick and easy access to the output report options available, but provide less introduction as to how data are entered into Lifeline and what data/knowledge requirements are placed upon the user.

A user could also open the pre-made files enclosed in the CD-Rom(s) in each, respective Lifeline module separately. This allows for a fuller exploration of the data inputs. The modules to enter and edit inputs are the Active Ingredient and Product Description, the Activity Description, the Food Residue Translator, and, the Tapwater Concentration module. In this way, a user would have an opportunity to explore the data inputs in detail, developing a clearer understanding of the type, amount, and quality of the data which could be used in the Lifeline model. The user could then move to the Risk-Dose and Exposure Reports modules (report generator). This method would require a moderate degree of time and effort by the model user.

And, lastly, a user could enter the data provided in the Demonstration Case independently. The user would open each module, the Active Ingredient and Product Description, Activity Description, the Food Residue Translator, and Tapwater Concentrations module and insert the information provided in the Demonstration Case (or data of their own choice) followed by the development of a hypothetical population in the Lifeline Model and evaluation of the analysis results in the Risk-Dose-Exposure Reports module. This approach is more time intensive, but presents an opportunity to fully appreciate the design, operation and reporting potential of the Lifeline software tool.

Examination of the software code: There are more than 90,000 lines of C++ code in the LifeLineTM Model. For this SAP, a portion of the LifeLineTM code (key calculation algorithms) was annotated and provided to the panel for their review.