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Overview of the Fundamentals of Version 1.0 of LifeLine™ Software for Modeling Aggregate and Cumulative Exposures to Pesticides®

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An Overview of the Fundamentals of the LifeLine™ V. 1.0 Software®

Page 1

Fundamentals of LifeLine™ Version 1.0

This document presents a brief overview of Version 1.0 of the LifeLine™ software system for the evaluation of aggregate exposures, doses, and risks associated with the use of a pesticide Active Ingredient. Using appropriate relative toxicity factors, the software can also be used to evaluate cumulative risks from multiple Active Ingredients.

LifeLine™ Version 1.0 is the first of many versions of the software, which will develop in response to scientific advances and suggestions from the software users. Versions 2.0 and modifications of 1.0, presently under development, will contain modifications such as: additional exposure opportunity modules, more contemporary dietary intake data, use and usage modules, improved interface screens for cumulative assessment exercises, and additional exposure factors as they become available. These versions, as with Version 1.0 will be made available to all interested users. These releases will be accompanied by a user support system to assist users and provide background information to encourage technically sound application of the software.

The Nature of LifeLine™ Version 1.0

The LifeLine™ software offers the first tool that can characterize population-based aggregate exposures and doses,¹ and estimate the toxic risks associated with those exposures. The software allows you to characterize the total aggregate exposures and risks from pesticide residues in diet, residential uses, and tapwater related sources. The model provides a powerful tool to understand the relative contributions of these sources and how they vary across individual's lives.

Using this version, you can examine:

- the history of each individual's exposures to a pesticide from all sources,
- the patterns of exposure for a population over time,
- the distribution of exposure across a population at any age and season, and
- the corresponding risks for non-cancer toxic effects associated with those exposures, as well as the lifetime cancer risks.

No matter which perspective on the data you select, you are able to consider:

- the contribution of oral, inhalation, and dermal exposure routes to total exposure,
- route-specific and systemic toxic risks,
- the contribution of food, tapwater, and residential uses to total exposure, route-specific risk, and systemic risk,
- typical and maximum exposures and associated risks, and

¹ The model allows you to input data on absorption from the gastrointestinal tract, respiratory tract, and skin. When data are provided, the model will automatically track aggregate dose. If no data are provided, then the model will track exposures.

- temporal averages of exposure² over any period of exposure between a single day and an entire year.

DATA FOR ANALYSES

The LifeLine™ model draws on data from a number of different American surveys of people and exposure-related factors. Information on daily activity and dietary patterns is used to evaluate specific daily exposures for an individual. These data include:

- Natality data ((Birth records) National Center for Health Statistics [NCHS]),
- Residential patterns (Current Population Statistics, US Census),
- The Third National Health and Nutrition Examination Survey ((NHANES III), also maintained by NCHS),
- American Housing Survey (US Census and Department of Housing and Urban Development),
- Nation Home and Garden Pesticide Use Survey (US EPA, 1992b),
- National Human Activity Pattern Survey (US EPA, 1994),
- The Continuing Survey of Food Intake by Individuals (CSFII), US Department of Agriculture (USDA,),
- Residential Exposure SOPs (US EPA, 1998), and
- *Exposure Factors Handbook* (US EPA, 1997)

In addition, the LifeLine™ model uses the following types of user-supplied information (not all of these data are required, but detailed data are accommodated when available):

- Data on annual or seasonal levels of pesticide residues in agricultural commodities and specific food forms of those commodities (e.g., cooked-canned vs. raw),
- Data on the reduction or increase of residues due to food processing,
- Annual or seasonal data on the fraction of crops that might have been treated with the pesticide,
- The residential uses of the pesticide,
- Physical and chemical properties of the pesticide,
- Frequency and levels of occurrences in ground and surface drinking water supplies,
- Dermal absorption, and
- Toxicity information (NOAEL, uncertainty factors, Food Quality Protection Act (FQPA) factor, and modifying factors) for different durations of exposure³.

² For this particular comparison, risk data are not relevant, as the toxic reactions associated with short-duration exposures are generally qualitatively different from those associated with longer exposures.

³ The LifeLine™ model has the ability to evaluate exposure for periods longer than one day. However, discussion of these system features is outside of the scope of this paper.

System Basics

Aggregate exposure and risk assessment addresses pesticide residues in foods and tapwater, as well as pesticide use in the home. This version performs this assessment through a series of linked modules. These modules perform the collection and aggregation of data, the exposure assessment functions and then, display of the assessments in tabular or graphical form:

- *Enter or Edit Model Inputs*, where you supply the system with the basic data and assumptions needed to conduct an exposure and risk analysis,
- *LifeLine Model*, where most of the analytical work is performed, and
- *Risk-Dose-Exposure Reports*, where you review your results, determine which perspectives (on a nearly infinite number of possibilities) provide the most informative description of your results, and save graphical and/or tabular reports of those analyses.

Enter or Edit Model Inputs

Active Ingredient and Product Descriptions

This module allows you to describe features of a pesticide Active Ingredient (AI) that influence its exposure potential, to enter data on its toxicity under different exposure regimens, and also to describe the End Use Product Equivalents (EUPes) that are used to control pests in residential settings. A series of “wizards” prompts you to describe the AI, the EUPes that contain it, and the application methods by which each EUPe is used to control particular pests in residential settings. The results are:

- a risk group file (*.rkg) used by the *LifeLine Model*, and
- a report (paper or electronic) describing your input data.

Food Residue Translator

This module was created to integrate information on residues in agricultural commodities (RACs), food forms, and foods as consumed. This module produces characterizations of the residues in foods as consumed. This unique capability allows you to determine how residues are likely to vary in foods given the use/usage information provided. The output of this module can be viewed directly, printed as a report, and exported as a dBASE or Excel file. It is also used as an input into the *LifeLine Model*. The design of this module allows the direct input of data or the use of properly formatted databases.

Viewing this file permits the initial check on the plausibility of the information supplied to the software, before an exposure assessment is conducted. A full display is produced of each food in the USDA survey that could contain an ingredient possibly containing the pesticide residue, and the magnitude of those possible residues. The plausibility of these residue distributions can be considered (or validated) prior to conducting an exposure assessment.

Tapwater Concentrations Module

This module allows you to provide a value or distribution of residue concentrations for three types of water supplies (public/private systems, private wells, or other sources). Separate distributions can be specified for:

- The three types of water sources
- The four Census regions,
- Urban and rural residential locations, and
- The four seasons.

This ability to describe the level and frequency of occurrence gives the user flexibility to enter data from a number of different sources including monitoring programs, watershed models, as well as simple screening models.

Activity Description

This module allows you to:

- select from the provided quantitative descriptions of the activities tracked in surveys such as the National Human Activity Pattern Survey (or inferred from data on pest pressure),
- modify the provided quantitative descriptions of one or more activities (including copying descriptions from one activity to another), specifying different quantitative descriptions of the same activity at different ages, and
- save an activity description file for use in exposure assessment and/or subsequent modification.

The field of exposure assessment is rapidly evolving, this module allows you to enter the new data on exposure factors into the model for parameters such as:

- inhalation rates,
- dermal transfer rates,
- clothing factors, and
- factors relating to hand-to-mouth exposures.

Separate values for these factors can be defined for each age and activity. Thus research on the exposure related behaviors of children of specific ages performing specific activities (playing, eating, or sleeping) can be directly incorporated an analysis using this module.

Main Module: The LifeLine Model

This module defines the exposed individuals and the daily doses they receive from each of sources. This module produces the large output files that describe the individuals' exposures and the factors used to determine these exposures. For each individual, unique exposure assessment calculations (iterations) are calculated: for each day of a year (365) X years of life (perhaps 80) X for each route of exposure (3). Each exposure assessment is also calculated as source specific exposure. If other exposure durations are chosen, another round of unique calculations are created, viewing the duration period as it moves along the lifeline, one day at a time. (Each of these unique calculations can be considered to be an "iteration", as related to previous exposure assessment procedures.)

These files are utilized in the final module, Risk-Dose-Exposure Reports, or can be exported and evaluated using data base programs such as Access or dBASE.

Risk-Dose-Exposure Reports

This module translates very large files produced by the main module into more easily used "views" of the data. These can be examined in either tabular or graphical form. You may save the view that you are examining, and export any view that you have generated. Tabular reports can be exported in either Excel or dBASE format, while graphs may be exported as Windows metafiles, bitmaps, or JPEG files.

Using the System to Generate Exposure and Dose Estimates

The LifeLine™ software combines a series of activities that have heretofore been conducted as independent assessments. The following sections provide a brief "guided tour" of the system as an introduction to such use.

This "tour" presupposes that you wish to evaluate all of the sources of exposure that are addressed by the system (food, tapwater, and residential pesticide use), and that you want to evaluate toxic risks associated with short-term exposures. This provides for a demonstration of all relevant software features and choices. Users who only wish to address one or two source terms have the option of "turning off" other sources when running the model.

No matter what analyses you will select, the program needs to be supplied with basic information about the product you are considering. You use the ***Active Ingredient and Product Descriptions module*** to supply key properties, including toxicity, of the Active Ingredient (AI) under consideration. (In the tutorial supplied with the software, such information is provided for the hypothetical chemical, Alpha, and exists as default data provided for illustrative purposes in *alpha.rkg*). This module is also used to supply descriptions of the residential usage of your pesticide AI.

- For *either* residential or tapwater exposures, you may specify the quantitative parameters for different activities or accept the default data provided with the system in *preliminary assumptions.acd*).
- If you wish to evaluate exposures from residues in food, you must either

⇒ use the ***Food Residue Translator*** to convert residues in commodities⁴, or
 ⇒ use one of the example files of food residues provided with the system (*ps*.res*).
 Obviously, these examples only support an illustrative review of the system;
 actual exposure evaluation requires that you specify the appropriate residue data.
 This module also allows you to easily view the inputs and outputs of this analysis,
 to print these reports, or to save them as Excel or dBASE files.

- If you wish to evaluate exposures from pesticides in tapwater, you will provide a value or distribution of concentrations to reflect, season, region, rural or urban setting, and type of water supply. (The demonstration provides hypothetical data for illustrative purposes in *alpha.twc*).
- Once you have appropriate input data, the main ***LifeLine Model*** will analyze daily exposures for all selected sources for all relevant routes of exposure on every day of life of each individual in a population that you describe. These exposure assessment files are now available for viewing in any way that the user finds most appropriate for the question at hand. A rich array of options for viewing the data are provided in the last module (Risk-Dose-Exposure Reports) or these can be exported for unique data examination, as the user wishes. This provides the opportunity for detailed consideration of the exposure calculations and the contributing factors to those exposure profiles. Sophisticated analysts will appreciate the opportunity to examine this full data base and the source information linked to the calculations.
- By using ***Risk-Dose-Exposure Reports***, you can translate the output files into a set of focused views, each of which captures a particular perspective on the calculated exposures and their associated risks. You may generate as many of these as seems appropriate, and display them in either graphical or tabular form. You may save the results for later use with this program, or export tables or graphs. Tabular reports can be exported in either Excel or dBASE format, while graphs may be exported as Windows metafiles, bitmaps, or JPEG files.

The Need to Document Your Analysis (Audit Trail)

The output of any exposure or risk analysis is more meaningful when it is directly linked to the data and assumptions that were used to generate it. LifeLine™ is structured so that the generation of output reports is linked to internal audit files maintaining the input data. If these files are overwritten, you will not be able to generate further outputs.

In addition to built-in audits, the assessor can document the analysis with narrative and filing information using the generous identification fields.

The main output of the *LifeLine Model* is called *Exposure.DBF* and captures exposure (or dose) data. The file can be very large (up to 10 megabytes), because it includes the seasonal average and seasonal maximum data for:

⁴ Whether these are specified for entire Crop Groups [e.g., cucurbits], Raw Agricultural Commodities (RACs) [e.g., raspberries], or specific Food Forms [e.g., canned cooked potatoes].

- Every season and year of each modeled individual's life,
- Separate values of exposure/dose for each route or exposure,
- Separate values of exposure/dose received from each source,
- Separate values of exposure/dose for one day exposures, and
-

up to four additional averaging periods (7-day, 30-day, annual, etc.). In addition to this file the LifeLine Model also produces files that track the intermediate findings of the analysis for each exposure/dose estimate. These include:

- The house in which a given individual was living,
- The specific record of daily activity dietary, records, and
- The person's characteristics (sex, height, weight, surface area, etc).

This information is stored in the five files that you can choose to generate⁵ in your analysis:

- Person demographics (Lives.dbf),
- Residential details (Lives.dbf),
- Dietary daily doses (Diet.dbf),
- Residential activities (Ractiv.dbf),
- Residential pesticide use (Respuse.dbf)

These files along with the input files create a complete record of the basis for the model's outputs. The basic input files are:

- Risk Group File (*.RKG)
- Activity Description File (*.ACD)
- Commodity and Food Residue File (*.RES)
- Tapwater Concentration File (*.TWC)

NOTE:

LifeLine™ is a *probabilistic* exposure analysis system. This means that each run, even with identical inputs, produces a unique pattern of outputs. For large sample sizes, the results of multiple runs will be very similar. Small sample sizes, however, may yield very different results for different runs.

⁵ Generating such files allow the user to document the basis for each exposure, dose, and risk finding but generating the files requires additional run time for the model. Thus the software allows the user the option of not generating the files.

Preserving Your Input Files

Fundamentally, the best way to preserve your input files is to ***not overwrite*** any input file that has been used in the analysis. If you want to modify an input file (for example, to conduct a “what-if” comparative analysis), use a different filename when saving the file.

Printing and Exporting Files

Each module allows you to generate or edit an input file and supports both the printing of the file [or corresponding report file(s)] and the export of the file to Excel '97 or dBASE format. Specific instructions are provided with the description of each component module.

Preserving Your Results

Once you have generated the (tabular or graphical) views of your results that you believe are most informative, you can also save them, export them, or print them as well.

Instructions for doing so are provided in the section that describes *Risk-Dose-Exposure Reports*. Each saved (as opposed to exported) report contains pointers to the input files that were used to generate it. Again, it is good practice to save all of the important views of your results, while printing or exporting these views may help in the creation of your exposure / risk analysis report.