USER’S MANUAL

LifeLine™ Version 4.4

Software for Modeling
AGGREGATE AND CUMULATIVE EXPOSURES
TO
PESTICIDES AND CHEMICALS
February 11, 2007

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LifeLine™ Version 4.4 provides an important modification to LifeLine™ Version 4.3 that allows the user to complete both the model run and a summary report within the same process. The user may now choose to generate a summary report as required for submissions to US Environmental Protection Agency’s Office of Pesticide Programs at the point of setting the parameters of the analysis. In Version 4.3, the option for the summary report could be elected only after the analysis was completed (still available). Now the user has the option to generate two unique reports. In LifeLine™ Version 4.4, the first summary report can be designed when the user specifies the parameters of the analysis, and the second can be designed after the analysis is complete and the results considered. There have been no other changes incorporated in this version.

This User’s Manual was written by The LifeLine Group with generous contributions of time and effort from Ms. Sheila Piper, Office of Pesticide Programs, U.S. Environmental Protection Agency. This Manual is intended to assist the users of this software to navigate through the various features of the programs within this software, enter their data appropriately, choose appropriate options for analysis, and understand the results presented in the model’s outputs and reports. LifeLine™ Version 4.4 includes the ability to run the Summary Report from the Deliver application. This feature will collect the user settings prior to the model run and automatically proceed to process the Summary Report at the conclusion of the base model run. This update is officially certified to work with Windows Vista. LifeLine™ Version 4.3 was the first public release since Version 2.0. All interim versions between Version 2.0 and 4.3 were developed for testing and development purposes.

Please see the LifeLine™ website (www.TheLifeLineGroup.org) for updates of this manual, additional technical documents, and upgrades for the software.

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1. INTRODUCTION

LifeLine™ Software for Modeling Aggregate and Cumulative Exposures to Pesticides and Chemicals is a tool for characterizing population-based aggregate and cumulative exposures and risks from pesticide residues in food and tapwater as well as in the home following residential uses. The software provides a powerful tool to understand the relative contributions from these sources, and how they vary across individuals' lives. LifeLine™ is a probabilistic model of aggregate and cumulative exposures to pesticides and other chemicals, which are applicable to the general U.S. and Canadian populations and select sub-populations. This software uses probabilistic techniques to model exposure, risks, and benefits for the general population or for selected subpopulations such as children, women of childbearing age, or the elderly.

The sources of exposure included in the model are diet, home environments, drinking and tapwater, residential pesticide products, pesticide users or an aggregate of all of these sources. Routes of exposure considered in the model are: inhalation, dermal penetration and oral from diet, child's mouthing behaviors.

LifeLine™ Version 4.4 is the most flexible dietary software available for pesticide and chemical exposure and risk assessments. Residue files created with DEEM™ software can be imported into LifeLine™ eliminating the need to re-enter data. EPA imported DEEM™ files into the LifeLine™ software and performed the dietary portion assessment for cumulative risks of organophosphorous pesticides.

The current update, LifeLine™ Version 4.4, builds upon the significant improvements of LifeLine™ Version 4.3 and provides an important modification that allows the user to complete both the model run and a summary report within the same process. There have been no other changes incorporated in LifeLine™ Version 4.4.

LifeLine™ Version 4.4 has also been tested and certified to run on the Windows Vista operating system. Support remains for Windows 2000 and Windows XP. EPA is currently using Version 4.4 to assess dietary, aggregate, and cumulative risks of pesticides.

1.1 About LifeLine™ Software

The LifeLine™ software was the first tool that could characterize population-based aggregate and cumulative exposures and doses, and estimate the toxic risks associated with those exposures. The software allows you to characterize the aggregate and cumulative exposures and risks from pesticide residues in diet, residential uses, and tapwater. The model provides a powerful tool to understand the relative contributions of these sources and how they vary across individual’s lives. Version 4.4 allows for direct importation of data files formatted for use in other software programs, thus minimizing the effort needed to move existing information into LifeLine™ dietary assessments. Using Version 4.4, 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
  • Temporal averages of exposure over any period of exposure between a single day and an entire year.

1.2 Generating the Summary Report in LifeLine™ Version 4.4

The primary enhancement in Version 4.4 is the ability to run the summary report from the Deliver application. In Version 4.3, the user would need to first perform a model run in Deliver. Once the run had completed in Deliver, the summary report was generated by opening the Risk-Dose Exposure reports application and beginning a second time consuming process to generate the report. With Version 4.4, the entire process can now be performed in Deliver via a single click. In addition to designing this summary report, the user has the option to design a second summary report after the analysis is complete and the results considered.

1.3 Important Features of LifeLine™ Version 4.4

The numerous new and improved features in LifeLine™ Version 4.3 are also found in LifeLine™ Version 4.4:

1.3.1 The summary report of key regulatory findings from a LifeLine™ model run uses a format developed jointly with the Office of Pesticides in EPA and contains the exposure and risk information currently used by the Agency in regulatory decisions. The report also provides additional information on the distribution of exposures across any subpopulation during any of the four seasons. Finally, the report presents information on the distributions of:
  • Chronic exposures;
  • Chronic risks associated with those exposures;
  • Lifetime average doses; and
  • Lifetime cancer risks.

1.3.2 Incorporation of the new definitions of raw agricultural commodities (RACs) and the EPA/USDA Food Commodity Ingredient Database (FCID) along with the USDA 1994-96,98 Continuing Survey of Food Intake by Individual;
1.3.3 LifeLine™ Version 4.3 includes EPA’s redefined listing of Raw Agricultural Commodities (crops), crop groups and food forms;

1.3.4 The foods in the Food Residue Translator and their linkage to the crops are redefined according to those in the Food Commodity Intake Database (FCID);

1.3.5 The ability to input water residues (for all but tapwater) in the Food Residue Translator;

1.3.6 The ability to enter residue data on a food basis as well as a RAC basis;

1.3.7 Improved ability to directly import data files formatted for use in DEEM™ v.2005, thus minimizing the effort needed to move existing information into the LifeLine™ dietary assessments; and

1.3.8 Ability to enter data on residential exposure using either English or metric units.

1.3.9 Expanded performance and capabilities including:
   - Increased speed of operation over Version 2.0;
   - Ability to simulate lifetime exposures for up to 20,000 individuals and to simulate exposures for up to 100,000 individuals for younger age groups;
   - Improved documentation of the key inputs and interim values for the random day estimates of dose; and
   - Increased transparency of input files.

Please note that because of these many structural changes to the crop listings, food listings and related pieces, residue files (.res files) created with previous versions of LifeLine™ are incompatible with Versions 4.3 and 4.4. In addition, DEEM™ files created with older versions of DEEM will not import into Versions 4.3 and 4.4. Finally, the option to perform a dietary assessment with the USDA CSFII 1989-91 food survey has been removed from Versions 4.3 and 4.4. If you wish to use these older files or databases, we recommend you maintain a copy of LifeLine™ Version 2.0 for that purpose.

Version 4.4 is part of the ongoing program to continually upgrade and improve LifeLine™ software based on the scientific advances and input from the stakeholder community. If you have comments or suggestions on the project, you may reach the development team at our web site: www.thelifelinegroup.org. This web site will also provide access to updates for the LifeLine™ program and related documents.

1.4 Using this Manual

This manual is divided into three parts: a review of the software (Chapter 2); a “walk through” of the use of LifeLine in a dietary assessment (Chapter 3); and a reference section that contains a detailed description of the use interface.
2 OVERVIEW OF THE STRUCTURE OF LIFELINE 4.4, ITS FILES, AND LOGIC OF OPERATION

2.3 System Hardware Requirements

LifeLine version 4.4 is an IBM-PC compatible program that runs on computers with the following requirements:

- Pentium III, 700MHz or higher;
- A minimum of 256 megabytes of RAM (512 megabytes or 1.0 gigabytes recommended);
- 200 megabytes of disk space for the system; and
- Up to one gigabyte of free space on the swap file’s hard drive may be required depending on the amount of RAM your system has, how much of it is free, and the size of the analysis.

LifeLine Version 4.4 has been designed to operate faster than Versions 2.0 and generally runs about 30% faster the Version 2.0 (update). However, you should remember that for a single individual, more than a million specific values of dose and risk may be generated in a lifetime (up to 35 route- and source-specific exposure estimates per day and more than 31,000 days in a lifetime of 85 years.) For a model run of 10,000 individuals, more than 10 billion estimates of exposure are determined. The faster the processor, the more RAM, and the shorter the access time for the hard drive, the better the performance of the software. A dietary run of 10,000 individuals for ages 0-85 years can be expected to require 2-4 hours on a Pentium IV, 2.2 GB processor and a gigabyte of RAM. If a Summary Report is added to the run, the processing time on the same machine will increase by an additional 2-4 hours.

2.4 System Basics

Aggregate and cumulative exposure and risk assessment addresses residues of one or more AIs in foods and tapwater, and in the home. This version performs this assessment through a series of linked but separate programs. These programs fall into three classes:

- Programs that allow the user to enter or edit model input;
- LifeLine Model; and
- Risk-Dose-Exposure Reports.

When you wish to assess a compound, you will begin by entering data using the input programs. Once the data are entered, you will run the LifeLine Model. Following completion of the model run, you will use the Risk-Dose-Exposure Reports program to analyze the data.
2.5 Programs Used to Enter or Edit Model Inputs

2.5.1 Active Ingredient and Product Descriptions

This program allows you to describe features of a pesticide Active Ingredient (AI) or chemical that influence its exposure potential, to enter data on its toxicity under different exposure regimens, and to describe the pesticide products containing the AI that are used in residential settings\(^1\). A series of “wizards” prompts you to describe the AI or chemical, the products that contain it, and the application methods by which each product is used to control particular pests in residential settings. The outputs created by the Active Ingredient and Product Descriptions Program are:

- A risk group file (*.rkg) used by the LifeLine Model; and
- A report (paper or electronic) documenting your input data.

2.5.2 Food Residue Translator

This program allows you to integrate information on residues of an AI in Crop Groups, Commodities, or Food Forms, as well as processing factors that affect ultimate residues, and information on AI usage. This program produces characterizations of the residues in foods as consumed, appropriate for the FCID CSFII data. This unique capability allows you to determine how residues are likely to vary in actual foods. The output of this program can be viewed directly, printed as a report, and exported as a dBASE™ or Excel™ file. It is also used by the LifeLine Model. The design of this program allows the direct input of data or the use of properly formatted databases. The outputs created by the Food Residue Translator are:

- A dietary residue file (*.res) used by the LifeLine Model; and
- A number of reports (paper or electronic) documenting your input data.

2.5.3 Tapwater Concentrations

This program supports the entry of distributions of the concentration of an AI across residences with different types of water supplies (public/private systems, private wells, or other sources) in each of four Census regions and four seasons and for both urban and rural settings. The outputs created by the Tapwater Concentration program are:

- A tapwater concentration file (*.twc) used by the LifeLine Model; and
- A number of reports (paper or electronic) documenting your input data.

2.5.4 Activity Description

This program allows you to select one or more of the activities tracked in the National Human Activity Pattern Survey and set the values of key exposure parameters associated with the activities as a function of the individuals’ age; and save your inputs as an activity description file for use in future assessments. This model allows users of LifeLine to

\(^1\) Residential setting include indoor environments, pets, lawns and gardens, and certain recreational locations (golf courses).
incorporate the latest science and policies on exposure related factors (such as hand to mouth behaviors). The outputs created by the Activity Description program are:

- An activity file (*.acd) used by the LifeLine Model; and
- A report (paper or electronic) documenting your input data.

2.6 Main Program: The LifeLine Model

This program defines the exposed individuals and the daily doses they receive from each of sources. This program produces the large output files that describe the individuals’ exposures and the factors used to determine these exposures.

2.7 Risk-Dose-Exposure Reports

This program translates very large tables of analytical results into more easily used “views” of the data. These can be examined as graphs or as tables. The graphs can in turn be saved as Windows metafiles, bitmaps, or JPEG files. The tables can be exported in either Excel™ or dBASE™ format. This program also creates the Summary Report.

The Risk-Dose-Exposure Reports module is also one of the applications where the Summary Report can be generated. In addition, a Summary Report generated via the model run in Deliver can be viewed again by using this module. The Summary Report creates a formatted report of select data that have been used by regulatory agencies. The report was developed with the staff of the USEPA and is intended to facilitate regulatory assessments.
3 A WALK THROUGH THE USE OF LIFELINE

This section walks the user through the use of LifeLine in performing a dietary assessment.

3.3 Performing a Dietary Exposure Analysis

Dietary exposure analysis software aids in the determination of pesticide exposure and risk in dietary and residential scenarios. Version 4.4 permits the user to import data files created in another software program, DEEM™ and run the LifeLine™ analysis without re-entering all of the information originally captured on the DEEM™ files. Once loaded into LifeLine™, amendments to the original file can be made and saved in LifeLine™ format.

Two files must be created prior to performing a LifeLine™ analysis. The first, denoted by an .rkg file extension, outlines the “Chemical Parameters and Toxicology” of the pesticide. Chemical and physical parameters are input primarily for residential scenarios but are necessary to some extent for dietary exposure scenarios as well. The second file to be created, denoted by a .res file extension, concerns “Residues” (and processing factors or % crop treated) of the pesticide. This is the more critical of the two input files and is directly involved in generating exposure estimates. Following input, commodity residues are translated into their equivalent for a variety of different foodstuffs. Both files must be saved following completion in order to be used in the subsequent LifeLine™ analysis.

LifeLine™ analyses can be run as a screen with a limited population size or full analysis with 10,000 modeled individuals. While running, LifeLine™ creates model individuals with associated characters such as: gender, race, ethnicity, birth residence region and setting, birthday, income quartile, physiological dimensions, dietary data, and physical activities. LifeLine™ uses some of these characters to estimate dietary exposures. Both life history and individual exposures must be saved as exposure.dbf and lives.dbf files in order to be utilized in subsequent processing.

3.4 Creating the Input Files for Chemical and Toxicological Properties (.rkg)

The following are the steps for creating the .rkg file used in the assessment.

1) Click Start, Programs, LifeLine™, Enter or Edit Model Inputs, Active Ingredient, and Product Description.
2a) If you are editing a file that was already made, click Cancel, click File/Open, double click on file, and go to Step 7.

2b) If you are creating a new .rkg file: Enter Active Ingredient Name (mandatory), and the CAS# (no dashes), PC Code or Comments (optional), and click Next.

3) Enter end-use products containing the active ingredient (optional) and click Next.

Note: This page is used for entering data on residential exposure used in assessments of aggregate/cumulative exposure.

4a) Under Chemical and Physical Properties, Enter Henry’s Law coefficient (unitless) or water solubility (mg/L) and vapor pressure (torr) at temperatures used for bathing (30-50C). If you wish to minimize volatilization (and omit the consideration of exposure from
indirect inhalation of tap water) use enter values for high solubility (>100mg/L) and low vapor pressure (>1e-30 torr).

4b) Enter either the Octanol-water partition coefficient (unitless), Molecular weight (g/mol), or, if available, the Permeability coefficient (cm/hr). Values should be for temperatures used for bathing (30-50°C). To minimize dermal penetration (and omit the consideration of exposure from indirect dermal absorption of tap water) use values of 1e^{-12} for the Octanol-water partition coefficient and values of >1,000 g/mol for Molecular weight.

4c) Enter Oral absorption (unitless), Inhalation absorption (unitless) and Dermal absorption (unitless). These represent the fraction of active ingredient that becomes a systemic dose via various routes. If you wish to estimate how much compound reaches body boundaries (exposure), leave at 1. If you wish to estimate how much absorbed, fill in with fractions. If route-to-route dose extrapolation is to be used, enter fractions for specific routes. Cumulative dose and risk estimates require routes to be filled in with 1. Saliva extraction factor (unitless) represents the efficiency of active ingredient removal from an object by saliva. A default of 1 suggests that complete transferal takes place. De minimis level (unitless) represents a threshold percent reduction of residues at which calculations are no longer performed. A level of 100 suggests that residues are not tracked once they diminish to < 1% of their applied amount. Once these data are entered, click Next.

5) For Toxic Hazard Data, the user may enter a Short-term (acute; 1-30 days) exposure averaging period and/or click cancer potency data and click Next. Go to step 6a for non-cancer, 6b for cancer, or click Finish and go to step 7.
6a) If you selected any of the toxicity data boxes, the wizard will take you to a window for entering toxicity data. In these windows, enter route-specific or systemic toxicity data. The “Toxicity measure” should remain at “No Observable Adverse Effects Levels (NOAEL)” concentrations. Also, leave the “Description of measure of toxicity” box as “NOAEL”).

Enter values for the various factors. The value for the “Uncertainty factor” (UF) is typically 100, 300, or 1000 (to account for inter- and intra-species variability and database incompleteness). The value typically entered for the “Modifying factor” (MF) is 1. The value for “FQPA factor” (Food Quality Protection Act factor) of 1, 3, or 10 (based on database for infant, children, and maternal effects). LifeLine™ will calculate RfD and Population Adjusted Dose (PAD).

Note: Route-specific toxicology data reflects the assessment of human health risk, not route of administration in a relevant toxicology study.

If you wish to limit the ages where the FQPA factor are applied enter age values that are less than 85 years in the “FQPA maximum ages” box. Once these data are entered click Next (or Finish).
6b) For Cancer toxicity, enter the oral cancer slope factors. If you wish to evaluate exposure that occur by other routes enter slope factors for other routes. Once the data are entered, click Finish.

7) After entering data, a final screen will pop up showing entered values.
8) Verify entries and save file as ___rkg.

9) Print out ___rkg for quality assurance/quality compliance purposes.

3.5 Creating .res Files

There are two ways of creating the .res files use in the dietary assessment, importing files created using DEEM™ and entering the data directly.

3.5.1 Residues (Translating from DEEM™.r98 file to LifeLine™)

The following are the steps for creating the .res file used in the assessment by importing the data.

1) Click on Start - Programs - LifeLine™ - Enter or Edit Model Inputs - Food Residue Translator. This will open the Food Residue Translator.

2) Go to File and select “Convert/Import Crop Residues/Factors”.
3) The property page will appear. Select the ‘Browse’ button to locate the DEEM™ .r98 file you wish to import. Click Next. The number of commodities, distributions, and food forms will appear. Click Finish.

4) The LifeLine™ food residue/translator will import crop residues and factors from DEEM™ into LifeLine™. This may take a few minutes, please wait. When completed, the following window will open and display the imported residue values.

5) Perform a QA/QC check to see if the residues, processing factors, and percent crop treated match the DEEM™ file. LifeLine has attempted to create a program that will
automatically import most DEEM™ files. However, because of the flexibility in the formatting of these files, it is possible that certain factors will not import correctly.

6) Go to Step 7 in the section 3.3.3 for instruction on how to “translate to food residue”.

### 3.5.2 Entering new residue or tolerance data for Tier 1 or 2 assessments

The following are the steps for creating the .res file by entering data directly.

1) Click on Start - Programs - LifeLine™ - Enter or Edit Model Inputs - Food Residue Translator

2) LifeLine™ will open a window where “Inputs” residues are ready to be entered and the “Season Selected” is “Annual”
3) Maximize this window

4a) In the “Residue #1 (ppm)” column, enter tolerances for each crop group.
4b) If you have any unique Raw Agricultural Commodity (RAC) tolerances, click on 1st column to left of crop group (highlight row), click on the black comb (Expands crops/commodities) on the toolbar, and enter tolerances for the individual RACs.

5) To enter data on the Percent of Crop Treated (Tier II) Factors, click on “Use Factor” check box and enter a value of the percent crop treated under between 0 and 1.0 in the column “Seasonal Use Factor”. Note: Use maximum values for acute and average values for chronic models.
6) To enter values for the Default Processing Factors, click on “Processing factors” check box and enter factors that modify tolerance residues under the column “Dehydration”.

(Default processing factors are currently: apples-dried=8.0, apples-juice/cider=1.3, apricots-dried=6.0, bananas-dried=3.9, beef-dried=1.92, cherries-juice=1.5, coconut-dried=2.1, corn grain-sugar/hfcs=1.5, cranberries-juice=1.1, grapefruit-juice=2.1, grape-juice=1.2, grapes-raisins=4.3, lemons-juice=2.0, limes-juice=2.0, lychee-dried=1.85, onions-dehydrated/dried=9.0, oranges-juice=1.8, papayas-dried=1.8, papayas-juice=1.5, peaches-dried=7.0, peanuts-butter=1.89, pears-dried=6.25, pineapples-dried=5.0, pineapples-juice=1.7, plantains-dried=3.9, plums-dried (prunes)=5.0, plums-juice (prunes)=1.4, potatoes/white-dry=6.5, tangerines-juice=2.3, tomatoes-dried=14.3, tomatoes-juice=1.5, tomatoes-paste=5.4, tomatoes-puree=3.3.)
3.5.3 Converting to Food Residues and saving .res Files

This section describes how the data that was entered or imported is used to create the final .res file.

7) Click “Translate to Food Residues”. LifeLine™ will switch to the “Outputs/Foods” output window.

8) Click on “Outputs/Reports” and then “Commodity/Factors.”
9) Confirm that RAC tolerances are appropriate.

10) On the menu, click File and then Save, and save (.res) in the appropriate subdirectory.

11) Export to Excel™ file for Quality Assurance/Quality Control purposes. Click File, then go down drop down list to Export Report. Save into appropriate subdirectory as an .xls file. Note: This output can be cut and pasted for utilization as Dietary Risk Assessment Appendix A

3.6 Running LifeLine™

This section presents the steps for running the dietary exposure analysis with the LifeLine Model.

1) Click on Start, Programs, LifeLine™, LifeLine™ Model. When copyright appears, click OK.
2) When main menu and file selection box comes up, find the .rkg file, and click Open.

3) Maximize Window.

4) Click “1. Analysis and Preferences” button and the following dialog box will appear:
The file “lives.dbf” documents the physiological characters of each individual that is modeled. The file “diet.dbf” identifies the daily dietary record used to simulate each individual’s dietary exposure on the last day of each season of the individual’s life. Full lives (>70 yrs) must be evaluated when evaluating carcinogenic risks. The number of lives can set for values up to 100,000. The number of lives increases the time for the assessment but increase the stability of the estimate of the 99.9th percentile. Larger number can be run when subpopulations for children are of interest (i.e. 1-2 year olds).

5) Click “Dietary” tab and the ’94-96, 98 CSFII Survey box will appear. Click OK.

Note: the “Every season of the year” option will allow the program to run more quickly than the “Daily” option. Assessments of single day exposures are not affected by the choice of Daily versus “Every season of the year” therefore choose the “Every season of the year” option. If you are assessing the distribution of chronic exposures (not just the average chronic) then select the “daily” option to provide the correct estimate of the distribution of chronic and lifetime exposures.

6) If you wish to generate a Summary Report for this analysis, you may set it up at this time. To do so, you will select the Summary Report tab on the Analysis Preferences dialog.
On the Summary Report Parameters dialog box, select all of the age ranges of interest and enter a report title and description. You may also select the exposure duration you wish to generate the Summary Report against. Please note that to add additional exposure durations, you must first select them using the Averaging Period / Toxic Hazard tab on the same dialog. Once you select an additional averaging period, that then becomes available to you as a valid exposure duration to select. The View Report button found on this page is used to re-open the already created Summary Report if you happen to close it by accident.

7) A box will open up prompting for the food residue file. Find and click “Open”.

8) The “2. Population Characteristics” tab will pop up (The selections will be “Both”, “All”, “All”, and “All”). Click OK.
9) A temporary display of LifeLine™ loading the population dependent distributions will appear. Loading will take from 1 -3 minutes depending on the speed of your computer. Please wait.

10) Click on “Start Analysis”. This will initiate the modeling of each person. These are displayed in the open box. The program will estimate the completion rate and display this as a slider bar.

11) If the Summary Report feature has been enabled in step 6 then once all the lives have been generated, the summary report generation process will begin. There will be a pause of 2-5 minutes while the application moves to the summary report process. The summary report process itself can take considerable time to complete on a very large run. It is
possible that the summary report can take even longer then the initial model run if a population as large as 10,000 has been selected. It is important not to close Deliver until this process is complete. On a slower computer, a Not Responding message could be reported by the operating system. This simply means that the program is engaged in a large calculation and unable to report progress to the operating system. Thus, a not responding message is generated and should be ignored. If the process is interrupted before it has completed, it can be processed again in the Risk-Dose Exposure Reports module.

12) Click “View Analysis Results” if you wish to view modeled individual data such as body dimensions, residence characters, dietary data, and activity. These data were used to calculate exposures.

13) The results from LifeLine™ summary report range from 4 to 15 pages depending on the opinions selected and the nature of the model run. The report includes user inputs, toxicological information, graphs, summary findings of each age category, and percentiles based on dose, MOE and percent RfD. Tables 3, 4, and 5 are the estimates for acute and chronic doses and risks based on the random 1-day doses that reflects the intra- and inter-individual variation in the simulated population for all four seasons. EPA has traditionally used these values in regulatory decisions. The following is an example of Table 3.

| Table 3. Estimates of Acute Doses and Associated Risks Based on Random One-day Doses for Select Percentiles of a Distribution that Reflects Intra- and Interindividual Variation in the Simulated Population for all Four Seasons ** |

<table>
<thead>
<tr>
<th></th>
<th>95</th>
<th>99</th>
<th>99.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose (mg/kg/day)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Ages</td>
<td>2.98E+02</td>
<td>6.38E+02</td>
<td>7.06E+02</td>
</tr>
<tr>
<td>Ages &lt; 1</td>
<td>3.01E+02</td>
<td>3.01E+02</td>
<td>3.01E+02</td>
</tr>
<tr>
<td>Ages 1 - 2</td>
<td>7.93E+02</td>
<td>7.93E+02</td>
<td>7.93E+02</td>
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<tr>
<td>Ages 3 - 5</td>
<td>7.96E+02</td>
<td>7.96E+02</td>
<td>7.96E+02</td>
</tr>
<tr>
<td>Ages 6 - 12</td>
<td>6.08E+02</td>
<td>6.38E+02</td>
<td>6.38E+02</td>
</tr>
<tr>
<td>Ages 13 - 19</td>
<td>2.54E+02</td>
<td>2.76E+02</td>
<td>2.76E+02</td>
</tr>
<tr>
<td>Ages 20 - 49</td>
<td>2.23E+02</td>
<td>2.06E+02</td>
<td>3.31E+02</td>
</tr>
<tr>
<td>Ages 50+</td>
<td>2.65E+02</td>
<td>3.23E+02</td>
<td>5.06E+02</td>
</tr>
<tr>
<td>MoE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Ages</td>
<td>1.68E+02</td>
<td>7.84E+01</td>
<td>6.28E+01</td>
</tr>
<tr>
<td>Ages &lt; 1</td>
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<td>1.66E+02</td>
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<tr>
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<td>5.28E+01</td>
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</tr>
<tr>
<td>Ages 6 - 12</td>
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<td>7.84E+01</td>
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</tr>
<tr>
<td>Ages 13 - 19</td>
<td>1.97E+02</td>
<td>1.81E+02</td>
<td>1.81E+02</td>
</tr>
<tr>
<td>Ages 20 - 49</td>
<td>2.25E+02</td>
<td>1.59E+02</td>
<td>1.31E+02</td>
</tr>
<tr>
<td>Ages 50+</td>
<td>1.88E+02</td>
<td>1.55E+02</td>
<td>9.84E+01</td>
</tr>
<tr>
<td>Percent RfD (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Ages</td>
<td>3.07E+02</td>
<td>1.28E+03</td>
<td>1.59E+03</td>
</tr>
<tr>
<td>Ages &lt; 1</td>
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<td>8.02E+02</td>
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<td>5.93E+01</td>
<td>7.62E+01</td>
</tr>
<tr>
<td>Ages 50+</td>
<td>5.31E+01</td>
<td>8.48E+01</td>
<td>1.02E+02</td>
</tr>
</tbody>
</table>
Once created, the summary report can be exported as a .pdf, Excel, or Rich Test Format basis using the save function.
4 REFERENCE INFORMATION ON THE USER INTERFACE OF LIFELINE™

The following section provides a detailed description of the user interface of the various programs that make up LifeLine.

The programs that make up LifeLine are required if 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. If you only wish to address one or two source terms, you have the option of “turning off” sources when running the model and skipping the corresponding sections of this document.

The LifeLine™ system requires that the following programs be used in the assessments of specific sources.

1. All assessments use Active Ingredient and Product Descriptions to enter data on the properties of the Active Ingredient (AI) being assessed, including toxicity, of the AI under consideration. This program is also used to supply descriptions of the residential usage of the pesticides that contain the AI of interest.

2. Assessments of either residential or tapwater exposures must specify the values for key exposure related parameters for different activities.

3. Assessments of food residues must use the Food Residue Translator to convert data on residues in commodities into data of residues in foods.

4. Assessments of exposures from pesticides in tapwater must specify the appropriate distributions of concentrations to reflect inter residential variation in residues using the Tapwater Concentrations program.

5. Once you have entered the appropriate input data using these programs, 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. You may also select to generate the summary report in this module. As might be expected, this generates some extremely large data files. These are not easy to interpret without extensive experience in using large databases.

6. By using the program Risk-Dose-Exposure Reports, you can extract a set of focused views from the output files, each of which captures a particular perspective on the exposures and their associated risks. You may generate as many of these as seems appropriate, and display them in either graphs or tables. This program also contains the Summary Report option. A summary report may be generated or a previously generated Summary Report may be opened (so long as the data have not been changed).
4.3 Using the Active Ingredient and Product Description Program

The Active Ingredient and Product Description program allows you to enter information on the chemical and toxicological properties of an AI and the residential products in which it is used. Other programs (described in later sections of the Manual) collect data on residues in agricultural commodities and in tapwater. The data you enter in Active Ingredient and Product Descriptions are captured in a special file, called a Risk Group file. The names of these files end with the extension *.rkg.

Unlike some existing residential exposure assessment methods, LifeLine™ evaluates the exposures to an AI from all pesticide products that contain the AI. Residential uses of an AI are described in terms of “end-use product equivalents” (EUPEs). A EUPE is one or more registered end-use products that have no significant differences in their formulations or method(s) of application, or pests controlled. The model is based on EUPEs to avoid problems where one active ingredient is used in a large number of identical commercial products. For example, there are a large number of 2,4-dichlorophenoxyacetic acid plus fertilizer (“Weed and Feed”) products for sale, all of which have the same amount of active ingredient and are applied in the same way. All of these products would be considered a single EUPE.

NOTE:
You must create a Risk Group file to describe your Active Ingredient, even if you are not specifying residential exposures. While data on residential use products are captured in this program, its primary function is the collection of compound-specific data on the toxicity and physical properties of the AT under evaluation.

4.3.1 Data (and Specific Files) Required

No file is required to begin the analysis. You may, however, open an existing risk group file (an example called ALPHA.RKG is shipped with the system), modify it, and save the results (either as a new risk group file with a different name, or replacing the original file

WARNING:
If you modify a risk group file and save it with the same name, you will lose the data originally stored under that name, making it impossible to audit the results obtained using the original file.

When you start this program, it assumes that you want to create a new risk group file, and automatically invokes the Active Ingredient Wizard. A wizard is an automated series of screens that guides you through the process of entering data on an AI. The Active Ingredient Wizard is described later in the Help system and in this section of the Manual.
Wizard Operation

All wizards have the same basic control buttons:

- **Back**: Return to the previous page (not operational on the first page of the wizard).
- **Next**: Proceed to the next window (will not be operational if a mandatory field has not been completed).
- **Finish**: Replaces Next on the last window of a wizard.
- **Cancel**: Discontinue the wizard (losing any entered data) and return to the main program window.

To load an existing file, click the Cancel button on the Wizard and then either click on the open file folder icon in the Tool Bar or select File/Open from the Menu Bar.

All of the data on the Active Ingredient, EUPEs that contain it, and application methods for those EUPEs will be displayed in the summary table in the right half of the program window. By using the tree structure in the left half of the window and either the Tool Bar or the Menu Bar, you can:

- Add an Active Ingredient to the Risk Group (You can only add a single active ingredient to any Risk Group in this version. Future versions of LifeLine™ will allow you to enter data on a number of different AIs).
- Remove an Active Ingredient (This will delete all information for the active ingredient);
- Modify the data for the AI including:
  - Name, other identifying information, or description;
  - List of EUPEs that contain the AI;
  - Physical/chemical properties of the AI; and
- Toxicological data for the AI.
- Modify the description of a EUPE;
- Add or remove an application method for a EUPE; or
- Modify the properties of an application method for a particular EUPE.

Each of these options involves the use of a specific wizard.

**Active Ingredient Wizard**

This wizard automatically opens when the program is started. It can also be invoked by highlighting the New Active Ingredient entry in the tree structure and choosing Active Ingredient/Add from the Menu Bar. Once an AI has been specified, this wizard can be invoked by clicking on the AI in the tree diagram on the left side of the main window, and then either clicking on the Erlenmeyer flask in the Tool Bar:
or choosing Active Ingredient/Modify from the Menu Bar.

This wizard has between four and eight component pages (the last four pages are optional, and correspond to different types of toxicological data that you may or may not wish to supply).

The first page, AI Identification, is concerned with identifying information, most of which is optional in this version (in future versions, it will support linkages to other databases). The second page, allows you to build a list of EUPEs for the active ingredient.\(^2\) (Their properties are described elsewhere; see Application Method for a EUPE.) You can also modify this list using the Menu Bar. The third page, Physical-Chemical Properties, captures data that are necessary for predicting exposures and doses from the AI when used in residential settings or present in tapwater. The fourth page, Selecting Data on Toxic Chemicals, allows you to specify type of toxicity data (short, intermediate, or long-term data on non-carcinogenic effects and lifetime carcinogenic potency) you wish to enter for the AI, and the appropriate exposure durations for each. Note if you are performing a cumulative risk assessment the toxicity information for the index chemical should be entered.

### 4.3.2 AI Identification

This page of the wizard provides four data entry windows:

1. **Name.** This is the only mandatory field, and is supplied with a default value “Your Active Ingredient.” Up to 50 characters may be used to name your Active Ingredient.
2. **Chemical Abstract Number.** This field is not currently formatted with dashes, but accepts up to 10 digits (i.e., for the pesticide Captafol, you would enter 2425061, not 2425-06-1). This field is optional.
3. **PC Code.** This field accepts up to 10 digits. This field is optional.
4. **Comments.** Up to 200 characters may be entered. Text is automatically wrapped within this box. This field is optional.

### 4.3.3 End Use Product Equivalents (EUPES)

This window contains (at the top) a list of all the EUPEs currently associated with the current AI. If you are not evaluating residential exposures, this list may remain empty. You may delete any item in the list by clicking on it to highlight it, and then pressing the Delete key.

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\(^2\) If you are not evaluating residential uses of a pesticide, you may skip this window entirely.
CAUTION:
If you delete a EUPE in this window, you will delete ALL information associated with it, including application methods and all the quantitative data associated with each.

The more fundamental operation is to add EUPEs to the list. You do this by typing in a name of up to 50 characters (replacing the default “Your product name,” optionally specifying a “Registration number equivalent” of up to 11 digits, and clicking on the Add button.

NOTE:
You may add multiple EUPEs with the same name to one AI. This may, however, complicate your ability to track the data entered on multiple EUPEs.

4.3.4 Physical-Chemical Properties

This is one of the more detailed windows in the Active Ingredient wizard. It contains three main sections, each of which requires numerical data relevant to calculating exposures to this chemical. However, if you are not investigating dermal and inhalation exposures associated with chemicals in tapwater it is not necessary to place the actual values. Instead, the recommended dummy values discussed below should be entered.

Volatilization from Water

The top section of this window captures data that are needed to predict the volatilization of your AI from tapwater (for example, in a shower). When assessing exposures from tapwater you should enter the following data:

- **Henry’s Law coefficient** (unitless form), which is the ratio of vapor pressure to water solubility, and reflects the steady state partitioning of a chemical between air and water at a given temperature or,
- **Water solubility** (in mg/l) and **vapor pressure** (in torr) independently, from which the model will calculate the Henry’s Law Coefficient.

Each of these fields accepts numerical data as decimal values or as scientific notation (e.g., enter 5.3e-7 for 5.3 x 10⁻⁷).

Because both vapor pressure and water solubility (and, consequently, the Henry’s Law Coefficient) are temperature dependent, you should enter values that were measured or estimated at temperatures appropriate to the temperature of water used in showering or bathing (30-50°C).

If you do not wish to evaluate indirect inhalation exposure to pesticide residues in tapwater, you can enter values for these parameters that will minimize volatilization. A

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3 The unitless form of the Henry’s Law coefficient can be obtained by dividing the Henry’s Law coefficient (expressed in Atm-m⁹ / Mol) by 41.
Dermal Absorption from Water

The central section of this window captures three physical-chemical properties that are used to characterize dermal exposure to a pesticide AI in tapwater (for example, during a shower or bath).

The parameters that are entered in this section are:

- **Octanol-water partition coefficient** (often referred to as $K_{ow}$), which is the (unitless) ratio of the solubility of the chemical in octanol and water (i.e., its partitioning between them under steady-state conditions);
- **Molecular weight** (g/mol); or the
- **Permeability coefficient** (cm/h).

The system will estimate the value of the Permeability coefficient ($K_p$) based on the values of $K_{ow}$ and molecular weight you enter. If you have data on the value of $K_p$ for the AI, you may directly enter a value.

If you do not wish to evaluate indirect dermal exposure to pesticide residues in tapwater, you can enter values for these parameters that will minimize dermal penetration. A value of $10^{-12}$ will result in very low dose estimates and will essentially turn this route of exposure off. This dummy value will not affect the estimate of exposure from ingestion of tapwater.

Parameters for Route-Specific Absorption

This portion of the window allows you to enter compound-specific data on the extraction and absorption properties of the AI. These inputs are the fraction of the exposure that is absorbed and contributes to the total systemic dose. These inputs provide the basis for estimating the systemic dose that occurs as the result of an exposure. These inputs are:

- **Oral absorption** (unitless) this is the fraction of the ingested AI that is absorbed and becomes a systemic dose;
- **Inhalation absorption** (unitless) this is the fraction of the inhaled dose that is absorbed and becomes a systemic dose (also referred to as lung clearance); and
- **Dermal absorption** (unitless) this is the fraction of the dermal exposure that is absorbed and becomes a systemic dose. The portion of the AI that is retained in the skin should not be included in this fraction.

Note if the dermal absorption of the compound is influenced by the form and composition of individual products, a EUPE-specific dermal absorption factor can be specified in the portion of the AIPD that enters data on the individual EUPEs.
In each case, the entered parameter represents the fraction of an exposure quantity that is absorbed (unitless, 0 <= x <= 1.0). Each of the fields will accept numbers in either decimal or scientific notation.

In assessments where the goal is to characterize exposures rather than the absorbed dose you should enter values of 1.0. The model will then estimate the amount of AI that reaches the body’s boundaries. In the case of inhalation exposures, this is the total amount in the air that is inhaled. For oral exposures, it is the total amount of AI contained in materials that are ingested. For dermal exposures, it is the total amount of AI contained in materials that reach the skin.

The decision for entering values for absorption should be based on the nature of the risk that is being evaluated. Evaluations of portal effects should be based on exposure rather than absorbed dose. Therefore, assessments of portal effects should enter values of 1.0 for the absorption factors.

In assessments where risks are being evaluated using measures of toxicity that are based on an administered dose that occurs by the same route then the use of a value of 1.0 is also appropriate. In this case, the use of a value of 1.0 does not imply that the all of the exposure is absorbed. Rather, it indicates that a similar fraction of absorption occurred in the toxicity study and in the exposure.

In assessments where toxicity data from one source is being used to evaluate exposures that occur by a second route (route-to-route extrapolation in dose), then route-specific data on absorption should be entered into the model.

Assessments of cumulative dose and risk calculated by LifeLine™ require toxicity data that is based on the administered dose. In these assessments the absorption fraction for all routes should be entered as 1.0. Where the dermal absorption of an AI in a EUPE has a dermal absorption different from the AI used in the toxicity study (that established the AI’s relative potency factor for dermal exposure) the difference in the dermal absorption can be accounted for using the EUPE specific absorption factor.

When values of 1.0 are used for the absorption factor the estimates of “total exposures” simply is a measure of the total amount of AI that reaches one or more boundaries of the individuals’ body.

One of the remaining two parameters is specialized for a particular set of exposure-related behaviors, while the other is used to enhance processing efficiency of the LifeLine™ model through use of a “de minimis” screen on exposures.

- **Extraction coefficient** (unitless) reflects the efficiency that the AI is removed from an individual’s hand, or other object, by saliva (for example, in hand-to-mouth behavior transferring a pesticide residue from a hand to an oral exposure); and
- **De minimis level** (unitless) represents the magnitude of reduction in available residues at which further calculation of residues is deemed unnecessary for
exposure assessment. For example, at a value of 100 the remaining residue of an AI on a residential surface is no longer tracked once the concentration diminishes to one percent of the applied amount.

**4.3.5 Selecting Data on Toxic Hazards**

This screen allows you to specify which, if any, measures of toxic hazard you wish to supply for your AI, and the exposure durations that are appropriate for comparison for these toxic hazard data.

You may specify data on non-cancer toxic hazards for up to three different durations (short-term, intermediate-term, and/or long-term) by clicking the appropriate check boxes. You may also choose to supply data for evaluating the carcinogenic risks associated with average lifetime exposure to the AI. If you choose to enter the toxicity data, the wizard will then go on to additional windows that allow you to enter the data. If you do not enter data on the AI’s toxicity then LifeLine™ Version 4.4 will only model estimates of exposure and dose and will not produce estimates of risk (MOEs, %RfD, or incremental cancer risk).

**Minimum and Maximum Exposure Periods**

When you enter data on the non-cancer toxicity for a specific duration (short-term, intermediate-term, and/or long-term), you must indicate the minimum and maximum exposure averaging periods to which these data apply. Short-term toxicity will always apply to a duration of one day and can be applied to a maximum averaging period of 364 days. Long-term toxicity has a fixed maximum of 365 days and a minimum of two days. Intermediate-term toxicity may apply to any averaging period between 2 and 364 days.

The selected periods must be non-overlapping. In other words, if your short-term toxicity data are applicable for exposure averaging periods of up to 10 days, the minimum exposure-averaging period to which intermediate-term toxicity hazard data would be applicable is 11 days, and so forth. Non-selected toxicity durations do not affect this rule. For example, you could define short-term toxicity as addressing averaging periods between 1 and 182 days, while long-term toxicity covered periods from 183 to 365 days (assuming that you did not select intermediate-term toxicity).

**Non-Cancer Toxicity Data**

Once the duration and type of toxicity data is entered, the wizard will open one or more windows that will allow you to enter the actual data. The same format is used in each window to capture data:

- A toxicity spreadsheet;
- Description of the measure of toxicity; and
- The ages where the FQPA factor should be applied.

The pages differ only in the title at the top right that indicates duration of the hazard data (short, intermediate, or long-term) you are entering.
Toxicity Spreadsheet

This spreadsheet consists of four columns and six rows. Each column corresponds either to a set of route-specific (oral, inhalation, or dermal) or systemic toxicity data. In each column, you enter four pieces of toxicity data (toxicity measure, uncertainty factor, modifying factor, and FQPA factor) that provides the basis for determining the reference dose (RfD) and the population adjusted dose (PAD).

For example, you may specify the following data for systemic toxicity in the short-term toxicity window:

- No Observed Adverse Effect Level (NOAEL) in milligrams per kilogram body weight per day;
- Uncertainty Factor (UF; unitless) that is based on the nature of the available toxicity data;
- Modifying Factor (MF; unitless) that is based on compound specific considerations; and,
- FQPA factor (unitless) that is based on specific toxicity concerns for children or women of childbearing age.

Based upon these data, the system will determine the values for the RfD using the formula:

\[ \text{RfD} = \frac{\text{Toxicity Measure}}{(UF \times MF)} \]

and PAD reflecting special concern for risks to children or from prenatal exposure using the formula:

\[ \text{PAD} = \frac{\text{RfD}}{\text{FQPA factor}} \]

The route-specific toxicity data should be based on the administered dose for that route. The route designations supplied in the table do not reflect the route of administration used in the underlying toxicology study, but rather address the applicability of the toxicology data to human health risk assessment. Data collected from a study using any route of exposure may be applicable to the assessment of toxic effects on a systemic basis, even when exposure occurs primarily by other routes.

The values of the systemic toxicity data can be estimated based on route specific data adjusted for the route specific absorption. Thus, if the toxicity measurement for the oral route is 10 mg/kg/day and the dose is understood to be well absorbed then the toxicity measurement will be the same for the systemic dose. For a poorly absorbed compound, the systemic toxicity would be higher than that indicated by the administered dose.

The values that you have entered into one cell can be copied and pasted to other cells. For example, if you wanted to specify the same values for both systemic and oral route-
specific toxicity the values in the oral column can be copied and pasted into the systemic toxicity column.

**NOTE:**
If you wish to evaluate total MOEs that reflect exposures from multiple routes of exposure using the systemic approach, you must supply a corresponding data set for systemic toxicity, if you prefer to use the route-specific measure of total MOE data on systemic toxicity is not required.

Description of Toxicity Measure

The measure of toxicity used as the basis of the RfD and PAD can be a No Observed Adverse Effect Level (NOAEL), a Lowest Observed Adverse Effect Level (LOAEL), the dose that produces an effect in 10 percent of the exposed population (ED_{10}), or a Benchmark Dose. For each Toxicity Measure that you have entered, you have the option of changing the relevant description, using the drop lists in the box on the lower left of the page. These descriptions are not used in the assessment but are tracked in the model documentation.

FQPA Factor Maximum Age

Because the FQPA Factor used to determine the population-adjusted dose generally reflects developmental toxicity or the special sensitivity of children to the toxic effects of the AI, you have the option of specifying the maximum age at which this factor will apply. If you specify an age less than the lifetime being evaluated, the PAD will be applied up to the cutoff age. After that age, the RfD will be applied in assessing noncancer risks. Because there may be concerns about differences between the sexes, or concerns about effects from prenatal exposures, separate ages may be specified for males and females.

Carcinogenic Hazard Data

Currently, EPA is evaluating cancer using two approaches a potency-based approach and a margin of exposure (MOE) based approach. This page captures information on the “potency” of your AI as a carcinogen (i.e., how quickly risk increases with increasing dose), on the confidence that the AI is in fact carcinogenic in humans, and on the source of the assessment of carcinogenic hazard. Again, data are captured separately for route-specific hazards and for systemic hazard. As in the case of non-cancer assessments, the latter value is the key factor for evaluation of risk from aggregate exposure.
NOTE:
If you wish to evaluate carcinogenic risks using an MOE approach then the estimate of the LADD produced by LifeLine™ should be used derive the distribution of the MOE for the compound using the formula:

\[
\text{MOE} = \frac{\text{Benchmark Dose}}{\text{LADD}}
\]

This can be done by exporting the data on LADDs and performing the calculation using a spreadsheet.

The rate of increase in risk with increasing exposure is expressed as the slope of a function that is presumed to be linear at low doses. This Slope Factor (sometimes referred to as a \(q_i^*\) or \(q^*\)) is entered in the left column of the spreadsheet, in the appropriate row.

The data entered in the remaining columns are the rating of the data on carcinogenic potency and the system used in setting the rating. There are two parallel rating systems used to designate scientific confidence that a particular chemical is carcinogenic in humans. The USEPA uses letters as primary designations, with numbers to indicate subdivisions, while the International Agency for Research on Cancer (IARC) uses the inverse approach. The categories are quite similar; the following table presents their general meaning, although there are subtle terminological differences.

<table>
<thead>
<tr>
<th>Evidence</th>
<th>EPA</th>
<th>IARC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known human carcinogen</td>
<td>A</td>
<td>1</td>
</tr>
<tr>
<td>Probable human carcinogen – human data</td>
<td>B1</td>
<td>2A</td>
</tr>
<tr>
<td>Probable human carcinogen – animal data</td>
<td>B2</td>
<td>2B</td>
</tr>
<tr>
<td>Possible human carcinogen</td>
<td>C</td>
<td>3</td>
</tr>
<tr>
<td>Not classifiable as to carcinogenicity</td>
<td>D</td>
<td>4</td>
</tr>
<tr>
<td>Evidence that not a carcinogen in humans</td>
<td>E</td>
<td>5</td>
</tr>
</tbody>
</table>

The middle column of the spreadsheet allows you to specify whether the source of the assessment of human carcinogenicity was EPA, IARC, or another source. The final column allows you to enter the designation of the weight of evidence. These data are not used in the determination of carcinogenic potency but is tracked and included in the model outputs.

**4.3.6 Identifying EUPEs**

This single-window wizard can be called by highlighting a EUPE in the tree diagram on the left side of the main window, and then either clicking on the yellow bottle in the Tool Bar:
or selecting End use product equivalent/modify from the Menu Bar.

The wizard presents the name and a Registration number (or its equivalent) for the selected EUPE. Either of these may be modified. While a EUPE may represent multiple products, LifeLine™ Version 4.3 only allows one number to be entered. While these names and numbers are not used in any of the dose or exposure calculations they are recorded in the outputs and are useful for tracking model results.

Application Methods and EUPEs

Each EUPE must have at least one application method. Multiple application methods can be assigned to EUPEs that are applied in different areas (indoors, outdoors, etc) or are applied in more than one way.

Most of the critical information that is used to describe the potential for exposure and dose is captured in the description(s) of these application methods. Separate application methods are required for products that are used in different residential settings. These settings (called Microenvironment Classes or ME Classes) are groups of residential locations or sites of pesticide usage. There are four ME classes in LifeLine™ Version 4.4: indoor locations, outdoor turf, outdoors (non-turf), and pets.

The same wizard is used either to add a new application method to a EUPE, or to modify an existing description of an application method. If you wish to add a new application method, you click on the EUPE (bottle symbol)

in the tree diagram at the left of the main window, and then either click on the spray can

or select End use product equivalent/Add application method from the Menu Bar. If you wish to modify an existing method, click on the application method (spray can) in the tree diagram at the left of the main window and then either click on the spray can or select End use product equivalent/Modify application method from the Menu Bar.

Each application method is described in terms of:

- A single combination of physical form and application method used in a particular class of Microenvironment;
- The pests against which it is used in this form in this ME class;
• The probability that the EUPE will be used to control a specific pest in an ME class; and
• Quantitative descriptions of applicator exposures and of amounts applied.

Physical Form / Application Method and ME Class

Each application method is assigned to a single combination of ME class, physical form, and application method taken from a list of 55 options. These options reflect a combination of:

• Four physical forms (dust/powder; granular; liquid; solid/collar);
• Nineteen application methods (hand, shaker can, bulb or bellows duster, drop spreader, belly grinder, rotary spreader, bomb, aerosol can, hand-pressurized pump sprayer, hose-end sprayer, trigger sprayer, dip, rinse, shampoo, directed-stream spray can, foam spray can, top spot, paintbrush, pour, and collar); and
• Four ME classes (indoor, turf, outdoors non-turf, and pets).

Because not all application methods apply to all physical forms or ME classes, the list of available types is shorter than would be expected from the combination of these lists. For example, hose-end sprayers are not used indoors, while top spot treatments and collars apply only to pets.

The system allows you to assign each EUPE any and/or all of these application methods, although it is unlikely that any actual product would apply to more than three or four application methods. Each application method, however, can only be assigned once for a particular EUPE. If you have two application methods that differ in their quantitative descriptions (see below) but have the same physical form, application method and ME class applicability, they should be described as separate EUPEs.

4.3.7 Pets

LifeLine™ Version 4.4 is limited to the assessment of exposures from the use of products on cats and dogs. It addresses applicator exposures and post-application exposures that occur by the dermal and incidental oral pesticide exposure pathways. The post-application exposures are assumed to occur because of direct contact with the pet. Indirect exposures to pesticide residues on objects or surfaces that occur as the result of pet contact with the surfaces or objects are not considered. In addition, this version does not address exposures from the application of pesticides to bedding areas and dog runs. The reason for this is the lack of data or an identified model on how individuals interact with bedding or dog runs.

Exposures to pesticides applied to bedding or dog runs that occur as a result of contact with the pets can, however, be evaluated. In this instance, you should enter the level of residue on the animal that occurs as a result of the use of the product on bedding or dog run.

On selecting an application method for pets, you will activate a drop-list that lets you select whether the EUPE / Application Method applies to either cats or dogs.
These choices are used to control the quantitative exposure to the pesticide following application. For a given mass applied to an animal, treatment of a dog results in a lower concentration of AI per given area of fur than the treatment of a cat. In contrast, a dog offers a larger surface area for exposure than does a cat. This version assumes that cats weigh 10 lbs and dogs weigh 30 lbs. Application rates entered into LifeLine™ Version 4.4 should be normalized to these pet weights.

4.3.8 Commercial Application

If you indicate that a particular application method for a EUPE is only applied by commercial applicators, the wizard will skip the screens that ask for information on Pests and Pest-Specific Use Factors and Exposures from Application and Harvest. Instead, you are presented with a window that asks the fraction of residences treated with the EUPE / Application Methods by region, for single- and multifamily homes.

Commercial Application Data

This window (the second window in the wizard if commercial application was indicated) contains two spreadsheets, each of which must be completely filled out. The upper spreadsheet asks for Use Factors (i.e., the probability that commercial application in this microenvironment uses this product and application method) for both single and multifamily homes in each of four Census regions.

The maximum value that can be entered for each cell is also displayed. For example, if a previously specified EUPE or application method had a Use Factor of 0.5 in the Northeast Region, the current EUPE / Application Method could not have a Use Factor greater than 0.5.

The lower spreadsheet asks for monthly use frequency data for both single and multifamily homes. Frequency can be expressed as a number greater than or less than one (the product being used more or less than once a month.) Separate values are entered for the warm season and cold season. The warm and cold seasons are based on the region of the residence using the following assumptions:

<table>
<thead>
<tr>
<th>Table Regional Market Share of EUPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region</td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
<td>Northeast</td>
</tr>
<tr>
<td>Midwest</td>
</tr>
<tr>
<td>South</td>
</tr>
<tr>
<td>West</td>
</tr>
</tbody>
</table>

Within a season, uses are assumed to occur regularly. For example, if you enter the use frequency of twice a month for both the warm and cold season categories, LifeLine™ Version 4.4 would assume that the pesticide would be applied approximately every 15 days around the year.
Non-Commercial Use: Pests and Pest-Specific Use Factors

In this window, you select the pest or pests that are controlled by this application method/EUPE (for non commercial products). For most application methods, you may select one or more of the 22 categories of pests. For pets, only fleas or ticks/chiggers may be selected (the other pests on the list do not specifically infest dogs or cats).

For each selected pest, you must specify a use factor that represents the probability that this application method of this EUPE will be used to treat that pest in that ME class. For example, if your trigger-spray liquid is used in 50 percent of the homes that treat for roaches indoors you would enter 0.5 for roaches.

The maximum factor column to the right displays the available use factor to be assigned, and reflects all existing descriptions of EUPEs and application methods. For example, if previously entered EUPEs and application methods had the following use factors for fleas:

- EUPE 1, application method 1 0.10
- EUPE 2, application method 1 0.15
- EUPE 2, application method 2 0.20

there would remain only a potential use factor of 0.55 for any other EUPEs and application methods. This would be displayed in the maximum factor column when entering the next EUPE or application method.

4.3.9 Exposures from Application and Harvest

This window collects data on potential exposure from application of the EUPE with the selected type of application method. (Note: This screen will not appear for the bomb application method, which is assumed not to have applicator exposures; neither will it apply for commercial applications.) Two alternatives for entering applicator exposures are provided. You can select either method by means of radio buttons at the top of the window.

If you have access to the Pesticide Handler Exposure Database (PHED) or other source of applicator exposures, you can directly enter inhalation and dermal exposure values using a number of different units.

Either of these values can be entered using (as) a point estimate or (as) a distribution. If the user selects the option of entering the data as a distribution, they will be taken to two additional windows that will allow them to enter an empirical cumulative distribution. For ease of use, the data on the percentiles and the corresponding values can be pasted in from an Excel™ spreadsheet.

If you do not have or do not wish to use PHED values, both inhalation and dermal exposures for applicators are specified as percentages of the applied mass (a number between 0 and 100).
4.3.10 Post-Application Residues

This window captures data on the amounts of the AI that enter the residential environment (released to indoor air or applied to indoor surfaces) from the use of the EUPE and the selected application method.

The amount released to air is specified directly as the Concentration of the AI in air in the microenvironment (in mg/m³) immediately after any exclusion period associated with use (i.e., at the point where the first possible post-application exposure could occur). This only applies to the indoor microenvironment class. LifeLine™ Version 4.4 does not evaluate inhalation post-application exposures for pesticides applied to pets, turf, and “other outdoor uses”.

The amount applied to a surface from a “crack and crevice”, and broadcast use is entered by providing data on two factors the Concentration of AI in each unit of the product that is applied (i.e., mg per liter, per gram, per pound), and Rate of product application (e.g., liters per linear meter for a crack and crevice spray, pounds per square meter for a broadcast granular).

The amount applied to a surface from a “spot treatment” use is entered by providing data on three factors, Mass of AI in each unit of the product that is applied (i.e., mg per liter, per gram, per pound), the Rate of product application (e.g., liters per linear meter for a crack and crevice spray, pounds per square meter for a broadcast granular), and Fraction of the area treated (unitless, between 0 and 1.0).

The amount applied to a surface from the use of a bomb, you specify the Maximum area (m²) treatable by a single container. The final parameter is the Minimum time for re-application (in days). This parameter (defaulted to zero) is used to ensure that probabilistic methods do not result in predictions of re-use that are precluded by label conditions.

Post-Application Residue Declines

The final window captures data on the decay in total and dislodgeable residues on surfaces following application. This window is applicable (and appears) only for application methods that deal with turf, indoors use, or pets. The values that must be entered are different for each of these three sites of use.

For indoor applications, you specify:
- Decline rate in dislodgeable AI mass on hard surfaces (percent per day);
- Decline rate in dislodgeable AI mass on soft surfaces (e.g., carpets; percent per day);
- Fraction of total AI mass that is dislodgeable from hard surfaces (0-1.0); and
- Fraction of total AI mass that is dislodgeable from soft surfaces (0-1.0).

For turf applications, you specify:
- Decline rate in dislodgeable AI mass on turf (percent per day);
• Fraction of total AI mass that is dislodgeable from turf (0.0-1.0);
• Decline rate in total AI mass on turf (percent per day); and
• Decline rate in total AI mass in soil (percent per day).

For pets, you supply:
• Decline rate in dislodgeable AI mass on the pet (percent per day); and
• Fraction of total AI mass that is dislodgeable from the pet (percent per day).

In this window, you also have the option of entering a value for a product specific dermal absorption factor and an oral modifying factor. The oral modifying factor can be entered as a distribution.

The oral modifying factor may be used for a number of different purposes. You may enter a value that adjusts saliva extraction for a specific product. Alternatively, you can enter a distribution that can capture the variation in one or more terms.

In this window, you also have the option of entering a value for a product specific dermal absorption factor and an oral modifying factor. The oral modifying factor can be entered as a distribution.

The oral modifying factor may be used for a number of different purposes. You may enter a value that adjusts saliva extraction for a specific product. Alternatively, you can enter a distribution that can capture the variation in one or more terms.

4.3.11 Results

As you answer the questions in the wizards, you are constructing two views of your data:
• A tree diagram on the left side of the main window, that shows the hierarchy of Active Ingredients, EUPEs that contain each AI, and application method(s) that can be used with each EUPE; and
• A table of descriptive and quantitative data for the AI, each EUPE, and each application method.

The tree diagram allows in the entering and revising of data on an AI’s EUPEs and their methods of application. The table is intended to allow a quick review of the values entered for an input and to serve as a summary. The table can be printed and included as part of the documentation of an analysis performed using LifeLine™ Version 4.4. However, the table cannot be edited directly. You should use the wizards to perform any needed modifications of inputs.

4.3.12 Saving a Risk Group File

Once you have completed the description of an AI, its EUPEs, and their application methods, you must “save” your data. The act of saving the entered data creates a compact file of the inputted data that has been formatted for use by the LifeLine Model program. The output file is called a risk group file and the names of these files end with .rkg. These
files will be saved in the location you specify. When you run the LifeLine Model program, you will be asked to specify the risk group file that the LifeLine Model will use.

To save the risk group file, either click on the diskette button in the Tool Bar

or select File/Save or File/Save as from the Menu Bar. It is best to save these files in the default (\workgroup) directory, as that is where the LifeLine Model will first look to find them.

**NOTE:**
Be SURE to save your entries as a Risk Group File. Unless you have saved the file, you will not be able to use this information in conducting an exposure or risk assessment.

The summary table that describes all of the information that you have entered regarding an AI, EUPE(s), and Application Method(s) can be printed as part of the “audit trail” of your exposure and risk analysis.

To print the table, either click on the printer icon in the Tool Bar,

or select File/Print from the Menu Bar. File/Print Setup in the Menu Bar can be used to adjust your printer to optimize printing of this file.

**4.3.13 Exporting the Summary Table**

In addition to saving your risk group (*.rkg) file in the internal format used by LifeLine Model and printing a paper copy, you may export the summary table in either Excel™ or dBASE™ IV format for later use. For example, you may want to import an Excel™ spreadsheet into a final report to facilitate the “audit trail” of your analysis.
4.4 Defining the Exposure Related Behaviors Associated with Specific Ages and Activities

Residential exposure assessments construct estimates of exposure and dose based upon a series of exposure and dose equations. These equations require that values for the equation’s inputs be defined. The values for some of the exposure factors are taken from data from various surveys or are entered by you using the various LifeLine™ input programs. In this program, Activity Description, you assign values to certain inputs (or exposure factors) that characterize exposure related behaviors. These include:

- Breathing rate categories;
- Dermal transfer rates;
- Effective dermal exposure duration;
- Clothing factors;
- Hand to mouth event rates;
- Fraction of hand placed in the mouth;
- Replenishment factors;
- Soil intake rates; and
- Grass intake rates.

The values for these factors are tailored to the specific macro activities defined in the National Human Activity Pattern Survey (NHAPS) and other exposure related activities (golf and pets). The factors are also linked to specific ages.

To enter the values or to review or edit previously entered values for the exposure factors, you must run Activity Description program. This program has been designed to assign values to exposure factors to all activities (both residential and nonresidential). LifeLine™ Version 4.4, however, only addresses residential exposure.

4.4.1 Data (and Specific Files) Required

No specific files are required to run this program. The Activity Description program exists to enter data on exposure factors, and the output of this program is an activity description file (*.acd). This file is used by the LifeLine Model program as the source of data on the exposure factors.

A set of initial values has been provided with the Activity Description program, in the file PRELIMINARY ASSUMPTIONS.ACD. This set of values was created based on the project development team’s review of recent EPA guidance documents, the team members’ professional experience, and historical practices in the field of exposure assessment. The values in this preset are intended to be “reasonable” worst case; they will
over-predict exposures for most individuals. The values are based in part on the “default” assumptions used in the EPA guidance and SOPs. They have not, however, been developed by EPA nor is any endorsement by the Agency implied.

The data set is supplied for a number of reasons. First, because of the level of effort required to enter age-specific values for the large number of activities in the NHAPS record, new users would be required to spend hours entering values before they could actually run the model. Therefore, this set of values is intended to be a support for new users. Second, the values are intended to be reasonably conservative estimates of the range of values that could occur. Therefore, if you are attempting to perform analysis with the goal of being “protective” may find the values to be a useful starting point (or base preset) for developing their own set of values (see below).

*These assumptions may or may not be appropriate to your assessments of exposure and risk. You may have alternative goals for the assessment, which may influence your selection of values.*

These assumptions may or may not be appropriate to your assessments of exposure and risk. You may have alternative goals for the assessment, which may influence your selection of values. In addition, new data, or alternative reviews of existing data, may lead you to adopting different values for one or more factors. You should develop your own set(s) of assumptions that are consistent with the available data and the goals of your assessment.

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**PRELIMINARY ASSUMPTIONS.ACD**

This file is shipped with LifeLine™ Version to provide an initial set of values for the exposure factors. These factors are offered as a set of plausible values that reflect historical practice. Because new data on exposure factors are constantly being published, and because the purpose of the assessment will vary from one application to another, the values in the file PRELIMINARY ASSUMPTIONS.ACD may or may not be appropriate for your assessment.

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**4.4.2 Structure of the Program**

In the LifeLine Model, data on exposure factors are grouped by the location where they occur. These groupings are called Activity Categories. Data on the values of exposure factors for multiple Activity Categories (locations) are contained in a single Activity Description File. LifeLine™ Version 4.4 addresses only activities that occur at the individual's residence (the residential activity category). The format that will allow the assessment of exposure at other locations has, however, been incorporated into the design of the Activity Descriptions program.

In an activity category, each of the activities that occur at that location is evaluated separately. Accordingly, the value for each of the exposure factors for an activity is assigned independently. In addition, the program allows you to specify how the values
for the exposure factors will vary across different ages. As a result, each activity category appears as a large table of activity-specific values for the exposure factors.

### 4.4.3 Creating an Activity Category

As noted immediately above, the current version of LifeLine™ only supports activity descriptions for residential settings. Correspondingly, only the Residential Activity Category is included in the file.

When you start Activity Description, you immediately launch a wizard that asks you to create a new activity category. It can also be invoked by highlighting the New Activity Category entry in the tree structure and choosing Activity Category/Add from the Menu Bar. Once an Activity Category has been specified, this wizard can also be invoked by clicking on the Residential Activity Category in the tree diagram on the left side of the main window, and then either clicking on the blue roof with figure in the Tool Bar:

or choosing Activity Category/Modify from the Menu Bar.

In the box at the top, you may specify a description of the nature of the assumptions that applies to all activity categories in this file (the default text that appears in this box reads “Your description”). This text is not used in the analysis but is there to assist you in documenting your analyses.

The second box allows the selection of the category for which you are describing activities. Since the current version of LifeLine™ only supports residential exposure a drop-box in the middle of the window only allow the selection of the residential category.

The final box allows you to select a “base preset” that will provide initial values for every activity in the category. A base preset is useful when you only wish to modify a few the values for a small number of factors or activities. You may select PRELIMINARY ASSUMPTIONS.ACD or any other set that you have previously saved as a base preset (see below).

Once your selections are complete, clicking on the Finish button will load the base preset values, and return you to the main program window.

Clicking on the Cancel button will also return you to the main program window; however, the tree structure on the left and the spreadsheet will be unchanged (if not base preset had been entered, the tree structure and spreadsheet will be empty).
4.4.4 Saving an Activity Category as a Base Preset

Once you have completed a description of an activity category, you have the option of saving your description as a “base preset” for future use. This is different from saving an activity description file, but can only be done once you have saved your description as an activity description file.

To save an activity category as a base preset:

- Make sure that you have saved the current values as an Activity Description (*.acd) file;
- Select Tools/View/Edit list of available base presets from the Menu Bar; and
- Click on the button marked Add current description to catalog.

Your description of the current Activity Category will appear in the list of available base presets.

**NOTE:**

If you attempt to use the same name for a description twice, the system will not overwrite the presets, but will tell you that you have already saved the current presets. To replace a named set of presets, you must first remove the existing named set (by highlighting it and clicking on the button marked Remove description from catalog) and then click on the button marked Add current description to catalog.

4.4.5 Loading an Activity Description File

If you have saved an activity description file, and wish to either review it or modify it for future use, you must either click on the open file (folder) icon in the tool bar

or use the File/Open command from the Menu Bar. This will present you with a list of all of the Activity Description (*.acd) files stored in the \RTL\Workspace directory. You may use this File/Open window as a browser window to locate Activity Description files in other directories or disks.

**NOTE:**

You do not need to open a saved file to use it as a base preset for a new Activity Category, providing that you have added the values to the list of base presets (see Saving an Activity Category as a Base Preset, above).

If you select the file PRELIMINARY ASSUMPTIONS.ACD, you will achieve the same result as if you had selected the default choices in the wizard for Creating an Activity Category.
4.4.6 Modifying Activity Descriptions

Once you have either opened an activity description file or created an Activity Category, you are free to modify the values of one or more of the exposure factors and the ages to which the values apply, for one or more of the residential activities. To do this, you expand the tree structure on the left of the main window to show all of the individual activities, and either:

- Copy the set of values for the exposure factors for one activity and apply them to another activity or activities; or
- Edit the value of the exposure factors for an activity.

Copying Activity Descriptors

Many different activity categories from NHAPS may have a similar potential to lead to exposure to pesticides. In order to facilitate the process of entering data on the more than 80 different activities, the system allows you to apply the set of one activity to other activities. To do this, click on the activity in the tree structure that you wish to copy to highlight it, and either click on the figure in the Tool Bar that is pushing on the side of its button:

or select Activity/Copy descriptor values to other activities from the Menu Bar.

Doing this calls up a single-window wizard. The top half of this window is a spreadsheet that displays the current values for the selected activity. In the bottom-half is a series of check boxes, one for each of the other residential activities in NHAPS. Clicking on each box will toggle a check mark on or off. Use these check boxes to indicate those activities to which you wish to assign the set of values given in the top half of the window.

After you have indicated all of the activities to which you wish to copy the description of the selected activity, clicking on the Finish button will complete the transfer and return you to the main program window.

Editing Activity Descriptions

Each quantitative description of an activity can be individually edited, by clicking on the activity in the tree structure, and either clicking on the figure in the Tool Bar that is touching its toes:

or selecting Activity/Modify descriptors from the Menu Bar.
This action calls up a wizard that allows you to change the existing values for this activity and edit the age ranges to which the values apply.

**Changing the Base Preset for a Single Activity**

The first window of this wizard allows you to select data for the activity from all of the available presets. Your choices in this window do not affect the description of any other activities. A checkbox at the top of the window is marked Reset all existing descriptor values for the activity with the base preset values displayed in the table below. Below this is a drop list with all of the available sets of presets. At the bottom is a list of the current parameters for the selected preset shown in the drop list. Changing the selection in the preset will change the values displayed at the bottom of the window.

By clicking on the checkbox, you can change the values for this activity to those of the same activity in any of the presets listed in the drop box. Because this will completely reset the description of the activity, if you click on the checkbox, the system will ask you to confirm your decision before proceeding.

**Further Changes from Base Preset**

If you have selected a new preset for your selected activity, an additional window appears in the wizard. It presents a radio button that asks you whether you have additional edits. If you select no, the Next button is replaced by a Finish button. If you select yes, you proceed to the window for editing age ranges.

**Modifying Age Ranges**

The descriptions of many activities will vary significantly with age. For example, Active sports means something very different for a 12-year-old than it does for an 80-year-old. Accordingly, the system allows you to create up to 85 different sets of values for an exposure factor for an activity (one for each year of age). In practice, most activities will require fewer descriptions covering broader age ranges.

In the second window of the wizard (the third if you have changed the base preset of the activity), you may redefine the age ranges for your selected activity. At the top of the window is an 85-year time line, with a red bar representing each transition from one age-specific pattern to the next. Blue bars indicate the beginning of the first range (birth) and the end of the last range (age 85). Using this window, you may do any of the following:

- You may move a transition age by dragging the corresponding red bar;
- You may subdivide an age range by double-clicking the time line in between bars; this will insert a new red bar; and/or
- You may combine two age ranges by double-clicking the red bar that separates them, causing the bar to disappear.

The age ranges resulting from your selections will be displayed in the table at the bottom of the window.
If you subdivide an age range, both resulting ranges will start with the same values as the original range. If you combine two age ranges, all parameter values for the combined age range will be cleared (even if the two ranges had the same value for a particular parameter).

Separate age categories are required whenever one or more of the factors change. For example, if the dermal transfer rate that applied to children aged less than six differed from that of older individuals, while a different clothing factor applied to children below age 2, then three age categories would be established: 0-2, 2-6, and 6-85.

**Editing Parameter Values**

Each activity requires you to provide values for eight exposure factors. These factors consist of one categorical value and seven numerical values. The exposure factors are as follows.

Activity class is a set of categories of general activity defined by Layton (1993) as part of an equation that predicts an individual’s inhalation rate. The set of categories are:

- Rest
- Sedentary
- Light
- Moderate
- Heavy

A drop-list appears in the table that allows you to define which of the categories applies to each age range of the activity.

**Dermal transfer factor** (1/hr) is a value related to the dermal transfer coefficient defined in EPA’s Draft Residential SOPs.

The dermal transfer coefficient is defined as the mass of AI that reached the skin or clothing of an individual performing an activity in a given unit of time, divided by the dislodgeable mass of AI contained in a given area of surface. The dermal transfer coefficient has units of cm²/hr.

The dermal transfer factor used here is defined as the dermal transfer coefficient observed in a relevant study divided by the surface area of the test individual. In the dermal exposure equations, the dermal transfer factor is multiplied by each individual’s surface area to produce a person-specific dermal transfer coefficient that is then used in the same way as in the Draft Residential SOPs.

**Effective dermal exposure duration** (hr) is a value between 0 and 24. The concept on which this input is based is that of saturation of the skin by a contaminant. Over long periods of time, the skin is believed to reach equilibrium with the contaminated surface. After this equilibrium occurs dermal transfer is equal to dermal loss and the net of effective dermal transfer goes to zero. This term allows the user to specify a time after which dermal transfer no longer occurs. Thus, if the duration of time spent in an activity...
is 3 hr and the effective dermal exposure duration is set at 1 hr, the dermal dose will be calculated as if the duration of the activity was 1 hr.

**Clothing factor** (unitless), is a value between 1.0 and 0.0 that represents the fraction of the mass of exposure that actually reaches the individuals skin. At the maximum value, 1.0, the individual is assumed to be unclothed or the clothing is assumed not to prevent dermal exposure. At the minimum value of 0.0, the clothing is assumed to be a completely effective barrier to dermal exposure.

**Hand-to-mouth frequency** (events/hr) represents the average number of times each hour that an individual in a specific age range who is performing the activity places some portion of the hand the mouth.

**Fraction of hand in mouth** (unitless) is the estimate of the average fraction of the hand that is placed in the mouth by an individual in a specific age range who is performing the activity.

**Replenishment ratio** (unitless) is defined as the ratio of the average mass of AI on the surface of an individual’s hand to the dislodgeable mass of AI on a residential surface the same size as the individual’s hand. If one assumes that a dermal contact of a hand with a surface results in the complete transfer of the dislodgeable fraction of an AI from the surface to the hand and that the hand re-contacts a fresh surface between each hand-to-mouth event, then the value of the replenishment ratio will be 1.0. If it is assumed that the hand repeatedly enters the mouth without being “replenished” by a contact to a fresh surface, then a value of less than 1.0 should be used.

**Soil intake** (mg/hr) is the mass of soil consumed per hour. The factor is only used in those activities that occur in outdoor locations.

**Grass intake** (cm²/hr) is the area of grass consumed per hour. The factor is only used in those activities that occur in outdoor locations.

At the top of this wizard window is a button (**View base preset descriptor values** or **View your descriptor values**) that toggles the display of parameters at the bottom between the values that you are currently editing and the presets that you selected earlier (either in this wizard or for the Activity Category as a whole). You may use the copy (Control-c) and paste (Control-v) commands to fill in the values in the edit table. You may also copy values from other tables or from Excel™ spreadsheets. You must complete the table of parameter values in order to activate the **Finish** button and exit the wizard. You may also choose to cancel at any time.

### 4.5 Saving an Activity Description File

Once you have completed your revisions of the exposure factor values for the activity descriptions, you may save your values as an **Activity Description (*.acd)** file. Unless you save such a file, none of the information that you entered will be used (or usable) in exposure assessments. Moreover, as noted above, saving this file is a prerequisite to
making the data in the file available as a preset for selection as a base set in future uses of this program.

**NOTE:**
Be **SURE** to save your entries as an Activity Description File. Unless you have saved the file, you will not be able to use this information in conducting an exposure or risk assessment.

To save the activity description file, either click on the diskette icon in the Tool Bar:

![Diskette Icon](image)

or select File/Save or File/Save as from the Menu Bar. It is best to save these files in the default (\workgroup) directory, as that is where the LifeLine Model will first look to find them.

### 4.5.1 Printing the Summary Table

The summary table that describes all of the information that you have entered regarding a set of residential activities can be printed as part of the “audit trail” of your exposure and risk analysis.

To print the table, either click on the printer icon in the Tool Bar:

![Printer Icon](image)

or select File/Print from the Menu Bar. File/Print Setup in the Menu Bar can be used to adjust your printer to optimize printing of this file.

### 4.5.2 Exporting the Summary Table

The table of activity parameters may also be exported as either an Excel™ or dBASE IV™ format file. To do this, click on any cell of the spreadsheet. This will activate the Export Report option under File in the Menu Bar. Clicking on this option calls up a dialog that allows you to select the directory in which the data should be saved (the default is the \RTL\Workspace directory), to specify a name for the file, and to choose Excel™ or dBASE™ format. Again, these files may be useful for incorporating into your risk assessment report, and establishing an “audit trail” for your analysis.
4.6 The Food Residue Translator (Defining Residues from Farm Gate to Plate)

The purpose of this program is to create a file of residues on food, as eaten, to be used in the assessment of human exposure to dietary residues. This food residue file is named using the suffix .res and will be imported into the LifeLine Model program that calculates the daily exposures for each person in the population of interest. In LifeLine™ Version 4.4, the system (both this program and the LifeLine Model) can address the FCID CSFII data.

The Food Residue Translator accepts user inputs (data, defaults, or assumptions) such as residues in agricultural Commodities [these were referred to as RACs, Raw Agricultural Commodities, in Version 1.1, following then-current EPA practice], data on percent crop treated, and processing factors that apply to various Food Forms of any Commodity. These inputs are used together with the recipe file (called a translation file for the 1994-1996, 1998 data) contained within the program to generate estimates of the possible residues in foods as consumed (e.g., beef stew). The ability to view these distributions of residues in foods “at the plate” is a capability provided for the first time by the software. Before proceeding to the exposure and risk assessment, the assessor now has the opportunity to review these food residue distributions and consider if the results are consistent with what is known about residue occurrence in these foods.

Another feature of this software is the ability to use seasonal information about pesticide use practices, seasonal-specific residue information, and seasonal-related food technology practices. This yields an estimate of seasonal variation in food residue concentrations that may be due to seasonal differences in sources of particular commodities (e.g., commodities that are imported at particular times of year), or that are grown in different regions with different pest pressures in different seasons. This feature can significantly improve the characterization of seasonal variation in food related exposures.

The purpose of this program is to create a file of residues on food, as eaten, to be used in the assessment of human exposure to dietary residues. This food residue file is named using the suffix .res and will be imported into the LifeLine Model program that calculates the daily exposures for each person in the population of interest. In LifeLine™ Version 4.4, the system (both this program and the LifeLine Model) address the FCID CSFII data, with their respective associated recipe/translation files.
4.6.1 Type and Format of Data Required from the User

No specific files are required. Because of the size of the data sets that are available for certain AIs and groups of AIs. The program allows you to input data using a dBASE™ format file that can be created using dBASE™ or Excel™.

To run this program, you must have information about residues occurring post-harvest in or on the agricultural product at some level of precision (Crop Group, Commodity, or Food Forms of a specific Commodity).

The system also accepts data on the probability of use of the pesticide (e.g., percent crop treated during a season or annually), and on processing factors (up to six separate factors for any Crop Group, Commodity, or Food Form) that may modify the residue values as the commodity travels through the food technology process toward the dinner plate.

No specific files are required because of the size of the data sets that are available for certain AIs and groups of AIs. The program allows you to input data using a dBASE™ format file that can be created using dBASE or Excel™.

To run this program, you must:

2. Have information about residues occurring post-harvest in or on the agricultural product at some level of precision (Crop Group, Commodity, or Food Forms of a specific Commodity).

The system also accepts data on the probability of use of the pesticide (e.g., percent crop treated during a season or annually), and on processing factors (up to six separate factors for any Crop Group, Commodity or Food Form) that may modify the residue values as the commodity travels through the food technology process toward the dinner plate.

4.6.2 How to Enter Data

The Food Residue Translator allows you to enter data in three ways.

Option 1 is to enter the data manually. This approach is useful if there is only a small amount of data to be entered. You can call up a display of one of three data entry spreadsheets. You may enter residues, data on probability of use and processing factors directly into the corresponding spreadsheet, for Crop Groups, Commodities, or Food Forms of a specific Commodity. A brief set of instructions appears on top of the display when you first call the program (or specify a new file) to assist in entering the data.

Option 2 is to import a data file with the necessary data on residues, probability of use and processing factors. This approach is more practical for AIs with a large number of uses. The Food Residue Translator accepts files in Excel™ and dBASE™ format.
Option 3 is to use the bridge capabilities and import files created with other software.

4.6.3 Option 1. Manual Data Entry Using the Spreadsheets Provided by the Food Residue Translator

This is a straightforward, if potentially lengthy, matter of typing in values. It is important to pay attention to the indicated season (or annual data) for which you are entering data and the level at which you are specifying data (Crop Group, Commodity or Food Form). Data entered at the cell level can be copied and deleted using the **Edit/Copy**, **Edit/Cut**, and **Edit/Paste** menu options. Ranges of cells can be deleted or copied by blocking the range and using the same menu options.

The **Edit/Insert Cell** and **Edit/Delete Cell** menu options also allow you to shift cells left (i.e., cell deletion) or shift cells to the right (i.e., cell insertion.)

The Data Input Window

Once you have selected a survey, you will be presented with the main window of the application. As you can see, the left side consists of a Control Panel that directs the display of input and output information, while the right side contains the spreadsheet in which you are entering data (or the report of system outputs).

![Data Input Window](image)

Selecting a Spreadsheet / View

The Control Panel has three main sections, as shown below.

At the top, the Survey addressed by the current translation (1994-1996, 1998) is identified.
In the middle is a set of radio buttons that allow you to specify a season (or annual data). At the bottom is a set of tabbed controls that allow you to select:

- **Inputs:**
  - Processing Factors
  - Use Factors (e.g., percent crop treated)

- **Outputs**
  - All calculated Residues in Foods
  - Reports

There is also a button that initiates the conversion of the data that you have entered about commodities into predictions of residues in foods as consumed.

**Input Controls**

When the **Inputs** tab is selected, you may choose between viewing, editing, or entering residues, use factors or processing factors in the spreadsheet, in one of three ways, either:

- Click the button(s) on the Control Panel,
- Click the corresponding icon in the Toolbar or
- Select the desired option from View/Inputs from the menu bar or use the View option on the menu bar.
Annual or Seasonal Data

A key decision is whether to enter annual or seasonal data (whether for residues, processing factors, or use probability). The default on startup is annual data. By clicking on the appropriate button in the Control Panel:

Annual | Spring | Summer | Fall | Winter

or by choosing a season under the Season from the menu bar, you can select any one of the four seasons, as well as annual.

Simplifying Seasonal Data Entry

When entering seasonal data, the differences between seasons may be small in comparison to the commonalities. In order to save the effort of repetitive data entry, the values entered for any season (or annual) can be copied to the corresponding spreadsheet for any other season (or annual). Thus, you can enter the data once, copy it to other seasons, and then make appropriate season-specific modifications. To do this, use Season/Copy Current Sheet to on the menu bar.

Controls Within the Spreadsheet

Changing the Level in the Hierarchy

When the program is opened, Crop Groups are displayed. This allows you to specify residue data for an entire Crop Group, which will then be applied to all Commodities of that group for which specific residues have not been supplied. Alternatively, the Crop Group display can be expanded to show its member commodities, so that residue data can be entered for a specific commodity and commodity parts (e.g., Orange Peel). To expand any Crop Group, click on the row number at the very left of the spreadsheet, then either click the expand hierarchy button on the Button Bar,

select Edit/Expand Row from the menu bar, or right-click on the mouse to get a pop-up menu. In a similar fashion, an individual Commodity display can be expanded to show the Food Forms of that Commodity.

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4 EPA has grouped crops by virtue of their botanical similarities that may be relevant to distribution, metabolism and retention of pesticide residues. Some data developed from study of one crop within a group may be extrapolated to apply to all members of that crop group.

5 Pesticide residues may segregate into selective parts of a crop. Also, different crop parts may travel through different subsequent food technologies. Thus, residue estimations and formal regulatory Tolerances may be either established for the intact whole commodity or established separately for the crop subparts.
Either operation can be reversed. To collapse these displays, select the row for the Commodity or Crop Group, and either use the collapse hierarchy button on the Button Bar,

or select **Edit/Collapse Row** from the menu bar, or right-click on the mouse for a pop-up menu, to hide Food Forms or Commodities, respectively.

**Caution**
Do not collapse rows when you are converting the RAC residues into food residues, see Section 4.9. All residues should be made visible by expanding the appropriate Food Forms and Commodities before calculating food residues.

**Entering Residue Data**
Residue values may represent the residue expected to exist at the point of agricultural production, at some point post-harvest, at some point along the food processing path or at the point of purchase or consumption. The value(s) you use may be single values representing an average, maximum, legal Tolerance (or Maximum Residue Level) or any other point value you wish to use. Alternatively, you may use a distribution of values that represent these same kinds of points of progress of the Commodity toward the consumed food.

Note that you may provide one set of residue value(s) to represent the entire year and all sources of the Commodities being considered. Alternatively, you may provide a separate set of value(s) to represent each of the seasons. This may be preferred if the crops originate in different geographies, depending on the season. Different geographies may present different pest pressures, pesticide use policies, or competing pest management practices. Even within a single growing region, seasonal variation in pest pressure and pest management practices may exist.

For any Crop Group, Commodity or Food Form, you simply type in a residue value into the first (or next empty) cell in the corresponding row of the residue spreadsheet, and press **Enter**, beginning with the column labeled “Res.# 1.” By using the arrow keys or **Tab**, you can move to the next column and enter a second residue, and so forth.
If “no residue” is expected to occur in or on the Commodity, you must decide how to represent that situation in the data entry. Your choices include:

- Entering a zero. This usually implies that absolutely no residue exists, also implying that the pesticide was not used on any part of the Commodity available to the consumer;
- Entering some numerical value at or below the test method’s Level of Quantification or Level of Detection and
- Entering one or more values derived from mathematical models that predict the residue values below the sensitivity of the test methodology.

Thus, the entry of residue values may be designed to reflect seasonal or annual residue expectations at any point in the food technology chain, and with or without regard to pesticide use or residue decline. You are encouraged to annotate the analysis to record their choices of data and procedures employed.

**NOTE:**

If you enter one or more zeroes as residues for a Crop Group, Commodity, or Food Form, LifeLine’s Food Residue Translator will ignore any information supplied for that Crop Group, Commodity, or Food Form about pesticide use probability. This avoids “double counting” of use probability data or residue dissipation factors. Appearance of the zeros implies that these considerations are implicit in the residue value entered here.

**Entering Data on Probability of Use**

Probability of Use of a pesticide reflects the actual agricultural science employed at the growing site. Such real-life choices are influenced by pest pressure, season, contractual obligations between grower and buyer, competing chemical or non-chemical pest control options, regulations at point of production or product destination and other professional judgments. The single value entered into this spreadsheet reflects consideration of all of these factors, synthesized into a single probability value for the total year, or for any separate season of the year.

If values are not supplied for the probability of use, the system assumes that the residue value(s) you supplied incorporate(s) any available information on probability of use.

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6 USEPA Office of Pesticide Programs provides guidance for how these choices are applied for regulatory purposes. See http://www.EPA.gov/oppts for relevant policy documents.
Entering Data on Processing Factors

Processing Factors represent the change in the concentration of the pesticide in the Commodity or Food Form as it moves from the farm gate toward the dinner plate. These may be simple processes such as washing or storing for some time. Even these simple processes may change the pesticide residue in or on the Commodity. There are many processing technologies employed in modern food production. Each may influence the residue concentration.

The Processing Factors spreadsheet in the Food Residue Translator provides six possible factors for your use. You may use one or more of these or create your own category. To do so, go to the View/Inputs/Processing Factor Names option on the menu bar. This option (active only when the Processing Factors spreadsheet is displayed) will call up a table where you may replace any of the existing names with your new process names. While you may enter a very lengthy name, only about 16 characters will appear in the table.

The operation of the Processing Factors is very similar to those for Residues and Probability of Use, and the selection of rows and expansion or collapse of the hierarchy is identical, as is the entry of values for any of the six possible factors.

4.6.4 Option 2. Importing Data Files for Residues, Probability of Use and Processing Factors

You may prefer to create an electronic file in lieu of direct manual entry. This is obviously advantageous if the data have already been stored electronically. Accordingly, LifeLine™ Version 4.4 supports data entry by means of cutting and pasting data from Excel spreadsheets.

A single file is used to import data on residues, probability of use and processing factors. Although the information captured is primarily numeric, it is supplied as text strings. The fields for this database are as follows:

| Table 4-1. Structure of Residue, Use and Processing Input File |
|---------------------------------|---------|-------|---------|-----------------|
| Field             | Type    | Length | Values | Notes               |
| Cropgroup        | Character | 2      | Code   | Mandatory          |
| Raccode          | Character | 3/6*   | Code   |                  |
| Foodform         | Character | 2/3*   | Code   |                  |
| Coverage         | Character | 1      | Code   | Season code (or annual) |
| Residue          | Character | 10     | ppm (mg/kg) |                 |

7 0= annual, 1 = spring, 2 = summer, 3 = fall, 4 = winter (see below)
Pfactor1 | Character | 6 | unitless
Pfactor2 | Character | 6 | unitless
Pfactor3 | Character | 6 | unitless
Pfactor4 | Character | 6 | unitless
Pfactor5 | Character | 6 | unitless
Pfactor6 | Character | 6 | unitless
Usefactor | Character | 6 | 0-1 (unitless)


For the 1994-1996, 1998 CSFII:
- Crop Groups codes can be read off of the system spreadsheets and are also found in the system database RTCG11.DBF;
- Commodities codes are in RTCGCO11.DBF and
- Food Forms codes are in RTCOFF11.DBF

**NOTE:**
While codes for Crop Groups and Commodities are unique, those for Food Forms are not (i.e., the same Food Form could apply to more than one Commodity). Each record in this database must have values for Crop Group of interest; Food Form Data must have both Crop Group and Commodity.

Each record in the database should represent a single residue, use factor, and set of processing factors. Care should be taken in entering the latter two types of values, as only a single value is used for each Food Form, Commodity or Crop Group addressed. In the case of multiple entries of such records, only the last item in the file is retained.
**TIP:**
You do not need to build a residue database from scratch! An easy shortcut is to use the spreadsheets in the program to enter a single residue for each Crop Group, Commodity, or Food Form of Interest for the appropriate survey (1989-1991 or 1994-1996, 1998). Then click on the top right corner of the spreadsheet. This will cause the entire spreadsheet to be highlighted. By pressing **Control-c** (the standard keystroke for “copy”), you can copy the entire spreadsheet. This can be pasted into an Excel spreadsheet (use **Control-v** for “paste”) and used as a template for entering residue data.

Once in the Excel spreadsheet, new data can be pasted into the rows. (Hint: use the **Paste Transpose** option from the Excel menu to paste in data that was originally in a column format!).

Once the data are in place, highlight and copy the data. Go back to the *Food Residue Translator*, again click on the cell in the top right corner to highlight the entire spreadsheet and paste (**Control-v**) the data from the Excel spreadsheet. The data will be pasted in the correct cells of the *Food Residue Translator*.

Note when pasting the data back, the Crop Group, Commodity, or Food Forms must be in the exact same position as the original data copied from *Food Residue Translator*. 
Residues for a Crop Group, Commodity or Food Form

Residue data are specified in the same way for all levels of the hierarchy. Each record will be assigned as specifically as possible; in the absence of specific information, the data will be assigned at the next highest level of the hierarchy.

To specify residues for a particular Food Form of a particular Commodity within a Crop Group, you would enter $n$ records containing the following data:

- Cropgroup (mandatory);
- Raccode (if left blank, residue is assigned to the Crop Group);
- Foodform (if left blank, residue is assigned to the Commodity [or Crop Group if no Commodity is specified]);
- Coverage (mandatory: controls assignment to particular season or annual file) and
- Residue (mandatory: units of ppm (mg/kg)).

All other fields in these records are left blank.

Probability of Use for a crop group or Commodity

To specify probability of use for a particular Commodity, you would enter a single record with the following data:

- Cropgroup (mandatory);
- Raccode (if left blank, probability of use is assigned to the Crop Group);
- Coverage (mandatory: controls assignment to particular season or annual file) and
- Usefactor (must be between 0 and 1).

All other fields in these records are left blank.

Note that Food Form is not generally of interest when assigning data on probability of pesticide use.

Processing Factors for a Crop Group, Commodity, or Food Form

To specify processing factors for a particular Commodity / Food Form, you would enter a single record with the following data:

- Cropgroup (Mandatory);
- Raccode (Mandatory);
- Foodform (If left blank, factors are assigned to all Food Forms of the Commodity that do not have individual values assigned.) and
• Coverage (Mandatory: Controls assignment to particular season or annual file).
  o Pfactor1 (Any nonzero value is valid, blanks are ignored [treated as 1.0]);
  o Pfactor2 (Any nonzero value is valid, blanks are ignored [treated as 1.0]);
  o Pfactor3 (Any nonzero value is valid, blanks are ignored [treated as 1.0]);
  o Pfactor4 (Any nonzero value is valid, blanks are ignored [treated as 1.0]);
  o Pfactor5 (Any nonzero value is valid, blanks are ignored [treated as 1.0])
    and
  o Pfactor6 (Any nonzero value is valid blanks are ignored [treated as 1.0]).

All other fields in these records are left blank.

Hierarchical Data Sets

Just as in the case of manual entry, data can be supplied in this file using the hierarchical structure (Crop Group, Commodity, and Food Form). To enter data for all Food Forms of a particular Commodity, you should leave the Foodform field blank. To enter data for all Commodities in a particular Crop Group, you should similarly leave the Raccode field blank.

The nature of the data will influence the level in the hierarchy at which you specify them. As in the case of on-screen data entry, when both generic and specific data are supplied, the specific data take precedence, and generic data are used when no specific data are available. For example, you might specify one set of residue data that would apply to the Commodity “raspberries,” and a different set of data for the Crop Group “small fruits and berries.” In this case, the Crop Group values would be applied to all members of the Crop Group except raspberries. The specific data entered for raspberries would take precedence over the generic data for the Crop Group.

In general, the strategy for entering values at more general levels of the hierarchy depends upon how many of the subsidiary values will be affected. If a Residue file is applicable to only two Commodities in a Crop Group with two dozen members, it is clearly more efficient to repeat the data entry than to specify empty distributions for all the Crop Group members for which it does not apply. Making such choices requires you to be familiar with the structure of EPA’s Commodity Vocabulary, as well as with the use of the AI you are evaluating.
4.6.5 Option 3. Importing Data Files Created by Earlier Dietary Assessment Programs

ASCII files created using DEEM™ software can be imported directly into LifeLine™ Version 4.4. To import files into LifeLine 94-96, 98 CSFII forms, select the File pull-down menus and select the Convert/Import Crop Residues/Factors option. The following Property Page window will appear:

4.6.6 Option 3. Importing DEEM™ Files into LifeLine™ Version 4.4

To import files into LifeLine 94-96, 98 CSFII forms, select the File pull-down menus and select the Convert/Import Crop Residues/Factors option. The following Property Page window will appear:

Clicking the Browse button opens the following standard Windows Search window. Using this window, find the DEEM file you wish to open. Note that all supporting Residue files referenced by the Dietary files must be in the same directory. Clicking on the Open button after selecting the file will begin the import process and return you to the Property Page window. The window will now show the number of commodities, food forms, and residue distributions to be imported.
Clicking on Finish begins the process of importing the data. Once complete the program returns the user to the input spreadsheet.

4.6.7 Saving Residue, Use Probability and Processing Factor Information

Once you have entered data on commodity residues (at Crop Group, Commodity and/or Food Form levels), you can save these data for subsequent use in the Food Residue Calculation or for modification later in time. Click on the diskette icon in the button bar:

![Diskette Icon]

or use the File/Save or File/Save As options from the menu bar.

This will save your input data in a form that you can recall for future analysis in the Food Residue Translator. To access this file later, select Open from the menu bar.

4.6.8 Calculating Food Residues from Commodity Information

The information applied to the screens for Residue, Probability of Use and Processing Factors supports calculation of the possible residues that could exist on food “as eaten” and reported eaten by respondents in the 1989-1991 and the 1994-1996, 1998 CSFII.
Initiate this analysis by clicking on the button on the Control Panel labeled **Translate to Food Residues**, or by clicking on the plate button on the Toolbar

or by selecting **Translate/Crop Residues to Food Residues** from the menu bar.

**Caution**

**Do not collapse rows before you translate Crop Residues to Food Residues.** All residues must be made visible by expanding the appropriate Food Forms and Commodities before calculating Food Residues. Failure to do this will prevent the Residue data from being counted in the dietary exposure assessments.

When the system has finished calculating the resulting Food Residues, it displays them on screen. (The Tab on the Control Panel will automatically change from Inputs to Outputs.)

In order to perform this analysis, the system uses all of the information provided by the user as described above and a set of Recipe files (for the 1989-1991 CSFII) or Translation files (for the 1994-1996, 1998 CSFII). These files indicate the mass-proportional contribution of all ingredients for each food reported as being consumed in the CSFII survey.

The system calculates residues in foods by randomly selecting a residue value from the appropriate residue distribution for each ingredient in the food (created from the Residue, Use and Processing Factors data), and calculating a net residue in the food based on the residue in each ingredient and its mass contribution to the food. For example, if only one Commodity (with a residue of 0.10 mg/kg of the AI) contributed any residue in the ingredients in the food, and it represented five percent of the mass of the food, the food would have a residue of 0.005 mg/kg of the AI.

Single values for the food residues will result if only single values were supplied for all Commodity residues. If distributions of residues were provided for Commodities, distributions of Food Residues will result. Up to 10,000 residues are calculated for each food residue distribution. From this distribution, a probability density function is determined to yield a characteristic residue value for each percentile of the distribution. These probability density functions are used in analyses of potential dietary exposures.\(^8\) The resulting exposure analysis reflects the true distribution of the original distribution of

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\(^8\) A detailed description of the mechanism of the creation of the density function and resulting representative residue values can be found in the technical documentation that is provided with the software.
residues. Thus, if the distribution is heavily populated with low residue values and contains only a few high values, the probability of drawing a high residue value for use in the exposure assessment will be accordingly small.

4.6.9 Saving Calculated Food Residues

The potential Food Residues calculated by the Food Residue Translator can be in a form that will be used by LifeLine to calculate exposure by way of the diet. Click on the diskette in the button bar

or use the File/Save or File/Save As options from the menu bar.

To access this file later, use the File/Open command from the menu bar or the file folder opening in the Button Bar.

4.6.10 Summary Reports of Results

This program generates four basic Report files. The first two record the information you supplied to the system and refer to the commodities at the farm gate or somewhere in the food processing chain. The second two are products of the Food Residue Translator calculations and refer to the potential residues in foods as eaten, using the information supplied about the commodities, use and processing. These files are:

- A list of Crop Groups, Commodities and Food Forms for which you specified data, including:
  - the residue value if single, or the notation “distribution” if a distribution was specified, any applicable Processing Factors and
  - the relevant Use Probability Factor, if any

- A table of residue distributions (where for those Crop Groups, Commodities or Food Forms where a distribution was entered rather than a single value). This table complements the data provided in the first report.
  - the first row of the table is its title
  - the second row displays the relevant codes for Crop Group, Commodity and Food Form in each column
  - the third row displays the number of zeroes in the distribution
  - subsequent values are non-zero residues

In addition to the system file *.res that is used by LifeLine, and has been designed for operational efficiency rather than external viewing.
The FoodRes Table is a list of foods with at least one nonzero residue (and the corresponding residues), this is identical to the display produced automatically or by clicking the Foods button and

- A table of the top 10 percent of Food Residues (i.e., the residues observed in the foods in the highest tenth of maximum observed residue).

Each of the four report options is listed under View/Outputs on the menu bar or Outputs tab/Factors button and radio buttons on the Control Panel. These reports are displayed as spreadsheets and may also be printed or exported for application to other data-utility files such as Excel.

The FoodRes and top 10% Tables consist of the Food Code and Food Name and select percentiles of the cumulative density function of the residues in each of the foods.

4.6.11 Entering Data at the Food Level

LifeLine™ Versions 4.3 and later have a new option. Residue data can now be entered at the Food Level rather than the RAC. This means that data from market basket survey of specific foods (chicken nuggets, cold cereal, muffins, cheese burgers, etc.) can be entered into LifeLine. These data are entered by directly modifying data in the FoodRes table. Like the RAC residue spreadsheet, the FoodRes Table can be directly edited or exported to Excel for editing.

The process of entering data on the Food Level is performed by the following steps.

First, the data on residues in foods is evaluated. For each of the foods surveyed, one or more RACs are identified.

Second, residue data are entered for each of the RACs. These data can represent either default estimates or simple dummy numbers. The food processing step is performed and the FoodRes Table is created.

Third, the food data from the survey is rank ordered and the values for the percentiles of the FoodRes Tables are determined (5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70,
Fourth, the food or foods that most closely match the food surveyed are selected. The data from the survey can then be pasted in over top of the residue values generated by the data entered at the RAC level. Any other foods with residues created from the RAC can have their residues replaced with zeros. The new file can now be saved and used to run a dietary exposure assessment.

**Caution**

*Note once this is done you must not recalculate the Food Residues, since this will overwrite the new data and return the FoodRes Table to the values derived from the RAC.*

### 4.6.12 Generating a Report

In order to generate reports (either input or output data), you must go to the Outputs tab of the Control Panel (or select View/Outputs from the menu bar).

If you have not yet calculated Food Residues, you will be warned that the system cannot display Food Residues that have not yet been calculated when you click on the Outputs tab, and the spreadsheet of Foods will be blank. You will, however, be able to generate reports of your inputs.

Clicking on either of the first two reports (Commodity/Factors and Commodity Residue Distributions) will display the appropriate report as a spreadsheet. Clicking on either of the two reports (All Food Residues or Top 10% Food Residues), will only generate a report if you have entered residue data and generated Food Residues. Otherwise, clicking on the corresponding button will result in a warning that Food Residues have not yet been generated, and the corresponding report will be blank. Once you have translated inputs into Food Residues (see above), the second two report options become available.

**Only a single report** is available at any one time. Generating a second report will overwrite the first report (but not the input spreadsheets). To switch back to the input spreadsheet, click the Inputs tab on the Control Panel or View/Inputs from the menu bar.
4.6.13 Printing a Report

Once you have generated and displayed a report, the Print and Print Preview options under File on the menu bar become active, and you may print out the report for review or use (for example, in establishing an “audit trail” for your analysis). Print Preview will first prompt you with a menu for the printer to which the report will be directed, and then display the report as it would appear under the settings currently applied to that printer.

4.6.14 Exporting a Report

The currently-displayed report may also be exported as either an Excel or dBASE IV format file. When a report is displayed, the Export Report option under File on the menu bar becomes active. Clicking on this option calls up a dialog box that allows you to select the directory in which the report should be saved (the default is the \RTL\Workspace directory), to specify a name for the file, and to choose Excel or dBASE format. Again, these files may be useful for incorporating into your Risk Assessment Report and establishing an “audit trail” for your analysis.
4.7 Describing Exposures From Pesticides in Tapwater

Assessing pesticide exposure from tapwater contamination using LifeLine™ Version 4.4 requires you to enter information on the distribution of residue levels across the nation’s residential water supplies. Specifically, the model requires data on the distribution of residue concentrations in each residence’s tapwater supply, as a function of Census region, season, and type of domestic water source.

Separate distributions are required for each combination of:
- Four seasons;
- Four Census Regions;
- Three water source types (public or private system, private well, other) and
- Two settings (rural and urban).

While the system is designed to accept a separate residue distribution for each combination of the factors above, residue distributions can be copied from any water source to one or more of the others.

Residue data are entered using a format similar to the format used in @Risk or Crystal Ball for entering an empirically defined distribution. This format requires you to specify a minimum (0\textsuperscript{th} percentile) and maximum (100\textsuperscript{th} percentile) concentration, and the concentrations that correspond to selected percentiles of a cumulative probability distribution for intermediate values. Up to 50 concentrations and corresponding percentiles can be specified. The model takes these data and performs a linear interpolation between the points on the distribution.

Using this format, you can enter data from empirically or parametrically defined distributions. Parametrically defined distributions can be entered by generating values for select percentiles of the cumulative distributions using Excel or other spreadsheet programs.

4.7.1 Data (and Specific Files) Required

To specify a set of tapwater concentrations of a pesticide for use in exposure and risk analysis, you must already have specified a Risk Group (*.rkg) file that contains basic information on the Active Ingredient(s) (AIs) that you are evaluating. (This file also contains information on residential use products containing this AI.) When you open the
**Tapwater Concentrations Model**, you will be asked to specify the Risk Group file to which the tapwater data will be linked.

Each Tapwater Concentration file must be linked to a single Risk Group file. You may create multiple Tapwater Concentration files that link to the same Risk Group file. However, in any one analysis, only one of the files can be used.

You will use *Tapwater Concentrations* to create a file with information on the concentrations of your AI. This Tapwater Concentration file (*.twc) is used in subsequent exposure analyses, and may be opened within *Tapwater Concentrations* to use as the basis of other such files.

### 4.7.2 Linking Tapwater Concentration Files to a Risk Group

The *Tapwater Concentrations* program is implemented as a series of wizards that modify the file contents. The main window of the program consists of a tree structure representing different water supplies, and a spreadsheet showing the concentration data that have been entered for those water supplies. Highlighting a water supply in the tree structure and using the Toolbar or menu bar options activates the different wizards.

When you start *Tapwater Concentrations*, you immediately activate a single-window wizard that allows you to specify the Risk Group (*.rkg) file to which these concentrations in tapwater apply.

You may either type in the full path name for the file in the window provided (e.g., C:\HRI\RTL\WORKSPACE\ALPHA.RKG), or you may use the **Browse** button to find the file you want. The default directory for both risk group and Tapwater Concentration files is \HRI\RTL\WORKSPACE, but you may store and retrieve these files from any directory.

After you have selected your Risk Group file, the **Finish** button on the wizard becomes active. Clicking on this button will close the wizard, and call up the Main program window.

### 4.7.3 Tapwater Concentrations Window: Tree Diagram and Concentration Spreadsheet

All of the information that you enter in this program is stored on a spreadsheet, which is presented for viewing on the right side of the main program window. When you have completed data entry, you may save or print these results. You need to click on the spreadsheet to activate the **Print** menu option. On the left side of the Main window is a tree structure that depicts the various types of water supply for which you may specify data. The tree structure also directs access to the data entry wizards.
4.7.4  **Tree Structure Choices**

As noted above, water supplies can be characterized in terms of four variables (yielding 96 different water supplies). These have been organized into the following hierarchical structure:

1. Risk Group
2. Census Region
   (Four regions: Northeast, Midwest, South, West)
3. Water Supply Type
   (Three types: Public or private system, individual well, other)
4. Season/Urbanization Combination
   (Eight combinations: such as spring urban, summer rural, etc.)

The selection of a risk group has been described above. Once you have selected a Risk Group, you may only change your selection by opening a different Tapwater Concentration file (using the *File/New* or *File/Open* commands on the menu bar, or the corresponding icons on the Toolbar.)

4.7.5  **View Risk Group**

This option is selected by highlighting the **Risk Group** at the top of the tree structure and then either clicking the Erlenmeyer flask with a magnifying glass on the Toolbar or choosing **Risk Group/View** from the menu bar.

When you do this, you will start the program Active Ingredient and Product Descriptions. Then you can open the Risk Group that you have named.

4.7.6  **Select Risk Group**

This option is available only if you have not yet selected a Risk Group (for example, if you started the program, then clicked the **Cancel** button in the Risk Group wizard). You activate it by clicking on the Erlenmeyer flask in the (empty) tree structure called **No risk group selected**

then, either clicking the **Toolbar** button with multiple flasks
or choosing **Risk Group / Select** from the menu bar. This calls the single-window wizard described above under **Linking Tapwater Concentration Files to a Risk Group**.

### 4.7.7 Entering / Modifying Distributions of Tapwater Concentrations

Once you have selected a Risk Group (causing the tree structure of water sources to be completed), you are able to enter or modify a distribution of concentrations for any of the 96 types of water supplies addressed by the system.

To do this, you must expand the tree (by clicking on the small boxes with “plus” signs) for one or more regions and for one or more source types (public/private system, well or other). This displays a set of eight combinations of season and urbanization.

By clicking on a single water supply category (e.g., spring urban values for public/private systems in the Northeast), you activate the controls that call the wizard for modifying or copying the distribution of concentrations for that water supply type. The Toolbar icon for modifying concentrations is a calendar with a water droplet

Selecting **Water Source / Modify contamination** from the menu bar has the same effect. The wizard that is called up by either of these actions contains two windows.

#### Number of Percentiles, Minimum and Maximum Concentrations

In the first window of this wizard, you will specify concentrations that are entered as the minimum (0th percentile) and maximum (100th percentile) values and the number of intermediate percentiles for which you wish to specify residue concentrations. For example, if you wanted to specify only maximum and minimum values, you would set this value to zero; if you wanted to specify maximum, minimum, and a concentration that corresponds to a single cumulative percentage, you would specify one. If you wanted to specify decimal values, you would specify nine. You may specify any number between 0 and 50.

The maximum concentration must be equal to or greater than the minimum concentration and you cannot enter concentration values for any percentile that are smaller than the minimum value or larger than the maximum values that you have specified.
Specifying Concentrations for Cumulative Percentiles

Once you have specified the number of percentiles, and the maximum and minimum concentrations, clicking the Next button brings you to the second and final window of this wizard. On the left of the window is a column of percentiles and corresponding concentrations. You may enter the percentile and the corresponding residue concentration directly into this table. The minimum and maximum residue concentrations entered in the previous window are shown at the top and bottom of this table. These values cannot be edited in this window; you can; however, use the Back button to return to the previous window and edit the concentrations for the maximum and minimum in that window.

On the right of the second window is a slide control that provides an alternative to typing in percentile values. Move the slide to the desired percentile value (the arrow keys on the keyboard give more precision than is possible with the mouse), click on the appropriate percentile cell in the left half of the table, and click the button marked Update current cell. The value shown above the slide control will be entered into the cell.

The system requires (and will notify you if you attempt otherwise) that both percentile and concentration values be entered in an ascending order. For example, the 25th percentile must be below the 20th percentile in the table, and so forth. Similarly, the concentrations must be entered so that the concentrations corresponding to higher percentiles are larger than those assigned to smaller percentiles. You may use any desired spacing for the percentile values. For example, you might choose to enter the 50th, 75th, 90th, 95th, 97.5th, 99th, and 99.9th percentile concentrations in order to capture the shape of the cumulative distribution at the upper end more accurately.

Once you have completely specified your cumulative percentile table, the Finish button on the wizard becomes active, and you may click it to return to the Main window and view your values in the spreadsheet.

Once you have specified concentrations for a water supply type, the icon in the tree structure changes color (from yellow to red) to indicate that non-zero residue data have been entered into the distribution for this water supply type.

4.7.8 Copying Distributions of Tapwater Concentrations

Entering concentration distributions for 96 distinct water supply types can be time-consuming, particularly when multiple sources have identical or similar concentration distributions.

In order to facilitate data entry, the concentration distribution for any water supply type may be copied to one or more of the remaining types of water supply. Thus for, example, if you know that you want to specify decimal values for all public/private water supplies, you could specify them for one, and copy the values to the others.
To copy the values for a water supply type to other types, click on the type that has the values to be copied in the tree structure, and then either click on the dropper in the Toolbar:

or choose **Water source / Copy contamination to other source** from the menu bar. This calls a single-window wizard.

At the top of the window, the cumulative distribution of concentrations for the selected water source type is displayed (as a check so that you can be sure of the values that you are copying). At the bottom of the window is a list of the other 95 water source types to which you might wish to copy these values. Clicking on the checkbox next to any water source type will toggle a checkmark on (or off, on a second click). As soon as at least one checkbox is clicked, the **Finish** button becomes active (the **Cancel** button is always active).

When you have finished indicating all of the water source types to which you wish to copy the indicated data, click on the **Finish** button. You will return to the Main window, and the values will be copied to the corresponding locations in the spreadsheet. As in the case of direct entry of values, the tree structure icons of those water source types to which values have been copied will have changed from yellow to red.

### 4.8 Saving a Tapwater Concentration File

In order to use your tapwater concentration data, either in the main analysis or as the basis of further files of tapwater concentrations, you must save the file. Either click the diskette in the Toolbar

or the **File / Save** or **File / Save As** options from the menu bar which allows you to save your file. **Save As** allows you to specify your own filename rather than the default filenames (RTTAPW#.TWC) provided by the system.

#### 4.8.1 Printing the Summary Table

If you click any of the cells on the spreadsheet that appear in the Main window to the right of the tree structure, you will be able to select the **File/Print** option on the Toolbar. Using this option, you can print a hard copy of the summary of the tapwater data used in the model. This printout of the tapwater data can be an important part of the “audit trail” of your exposure or Risk Assessment.
To print the table, click on any cell in the spreadsheet and either click on the printer in the Toolbar

or select **File/Print** from the menu bar. **File/Print Setup** from the menu bar can be used to adjust your printer to optimize printing of this file. **File/Print View** allows you to preview the hard copy before printing.

### 4.8.2 Exporting the Summary Table

The table of tapwater concentrations may also be exported as an electronic file in either an Excel or dBASE™ IV format file. When the spreadsheet is selected, the **Export Report** option under **File** on the menu bar becomes active. Clicking on this option calls up a dialog that allows you to select the directory in which the file should be saved (the default is the \RTL\Workspace directory), to specify a name for the file and to choose Excel™ or dBASE format. Again, these files may be useful for incorporating into your risk assessment report and establishing an “audit trail” for your analysis.
4.9  The LifeLine™ Model Characterizing Daily Exposures Over The Entire Lifetimes of Populations and Individuals

The LifeLine Model program is the “heart” of this suite of software programs. It creates the exposure histories of statistically representative individuals that make up a user-defined population. These histories define the daily exposures that occur on each day of each individual’s life from birth to any desired age, addressing where each individual lived, what she or he ate, what she or he did and how those actions brought her or him into contact with pesticides from any or all of the three sources addressed by the model: pesticide residues in diet, the residential environment and tapwater supplies. The program allows you to tailor the assessment to the sources and populations of interest. The output of the LifeLine Model program is a series of files that describe each individual’s exposures over his or her entire lifetime. These files are used to assess the individuals’ doses and risk in the final program Risk–Dose–Exposure Reports. In addition, the output files can be directly analyzed using spreadsheet or database programs.

4.9.1  Data (and Specific Files) Required

The data files that are required by the LifeLine Model depend upon the nature of the analysis that you are performing.

All analyses require that you provide a Risk Group file. Risk Group files are created using the Active Ingredient and Product Description program shipped with LifeLine™ Version 4.4 and have the file extension *.rkg. Risk Group files contain the toxicological and physical/AI data on your Active Ingredient (AI), as well as data related to residential uses. The LifeLine Model program prompts you to designate which Risk Group file to use in your analysis and shows the Risk Group files that have been defined.

If you model exposures from residues in food (dietary analysis), you must identify a Dietary Residue file. These files are created using the Food Residue Translator program shipped with LifeLine™ Version 4.4, and have the file extension *.res. Dietary Residue files contain data on the distributions of pesticide residues in or on foods as they are consumed. The LifeLine Model prompts you to supply this file and show Dietary Residue files that have been previously created.

If you model exposures from residential pesticide use, you should provide an Activity Description file. These files are created using the Activity Description program shipped with LifeLine™ Version 4.4, and have the file extension *.acd. These files provide
values for the exposure-related behaviors associated with each of the residential activities in NHAPS. The program prompts you to designate which Activity Description file to use and shows Activity Description files that have been previously created. If you do not specify a file, the LifeLine Model program will use the file PRELIMINARY ASSUMPTIONS.ACD shipped with the system (the system includes a warning before this happens).

If you model exposures from tapwater, you must provide a Tapwater Concentration file. These files are created using the Tapwater Concentrations program shipped with LifeLine™ Version 4.4, and have the file extension *.twc. These files contain data on the variation in tapwater concentrations for different types of residences. The program prompts you to supply a Tapwater Concentration file, and shows Tapwater Concentration files that have been previously created. If you do not select a file, the system will not model any exposures from tapwater.

A detailed description of the Input files, and the ways to create or modify them, is provided in preceding sections of this tutorial. Eliminating tapwater sources or dietary sources removes the need for the corresponding files. All analyses, whether or not they involve residential sources, require a Risk Group (*.rkg) file. If residential sources of exposure are to be considered, this file must contain descriptions of the residential products containing the AI.

The main display of the LifeLine Model lists the files that have been selected as the basis for running the analysis in the window at the bottom of the display. This display window indicates the filename, path and the date and time of the last modification to each of the files. This is important for the “audit trail” of your analyses. The date and time of the most recent modifications are provided to allow you to track which version of a file was used in the analysis.

TIP:
Modifications of the Input files (i.e., Risk Group files, Food Residue files, Activity Description files, and Tapwater Concentration files) will not take effect when the LifeLine Model is in operation. These files are loaded either just before or immediately after selecting Analysis Preferences. If you wish to modify these files (or select alternative files) after starting an analysis with the LifeLine Model program, you must return to the Analysis Preferences step after saving the new versions of these files. Risk Group files need to be loaded by using File/Open.
4.9.2 Structure of Program Choices

There are five numbered buttons on the main display of the LifeLine Model program. Each of these buttons represent a step in the running of the program, beginning with your selection of the type of analysis and ending with the activation of the Risk-Dose-Exposure Reports program that allows you to easily explore the results of the analysis. These steps are generally designed to be performed in sequence. With one exception, each step becomes active when a preceding step has been completed. The exception is step “4. View Analysis Report”. This step can be skipped. In addition, you can go back to a previous step and change your inputs and decisions entered during those steps.

Interface buttons 1 and 2 set the conditions for your analysis, button 3 starts the simulation running, and buttons 4 and 5 provide for viewing and/or storing the results of that simulation.

4.9.3 Setting up an Analysis


Button 1. Analysis Preferences

Clicking on 1. Analysis Preferences opens a new window. This window has been subdivided into four basic areas, represented by a tabbed interface. The first Tab, General allows you to select the sources to be addressed, the data files to be maintained and the fundamental descriptions of the population (or individual) to be characterized. The remaining three Tabs address the options for modeling dietary patterns and residential activities, and selecting exposure durations to be evaluated.

Sources and Aggregation

One of the first choices you will want to make is to specify the sources of exposure that will be evaluated in your model run. Checking the appropriate checkboxes in the upper left box of this Tab allows you to select any combination of dietary (food), residential use, and tapwater-based exposures.

The selection of the diet and residential sources are straightforward (see Table 6-1). The selection of tapwater exposure, however, is more complex. Tapwater exposures draw upon data that are also used to characterize dietary and residential exposures. Further, tapwater exposures can occur from both oral and non-oral exposures. LifeLine™ Version 4.4 allows you to either to investigate all routes of tapwater related exposures, to examine only the oral route or to examine only non-oral exposures.

In this version, both Dietary and Residential Activity files are required if a complete evaluation of tapwater is to be generated. To reflect this dependency, the Tapwater checkbox is positioned differently from those for dietary and residential exposure. This
reflects the fact that tapwater exposures draw upon data that is also used to characterize dietary and residential exposures.

If you wish to run the LifeLine Model program only for tapwater exposures, and to examine all routes of exposure, you must place checks in the boxes for all three sources and provide Risk Group files and Dietary Residue files with zero values. This can easily be done by creating Risk Group files with no data on residential products and creating Dietary Residue files with no residue data. A Dietary Residue file that only includes zero levels of residues (NULLFOOD.RES for the 1989-1991 Continuing Survey of Food Intake by Individuals (CSFII) and NULLFOOD11.RES for the 1994-1996, 1998 CSFII) is included in the files shipped with LifeLine™ Version 4.4.

If you only wish to evaluate the oral (direct ingestion) routes of exposure you can “check” only in the Dietary and the Tapwater checkboxes. If you only wish to evaluate the non-oral exposure (dermal and inhalation exposures during showering and bathing) then you should “check” only the Residential and the Tapwater checkboxes. The following table provides a description of how each combination of sources should be modeled.
Table 6-1. Modeling Specific Source(s) with the *LifeLine Model Program*

<table>
<thead>
<tr>
<th>Source</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>Place a “check” in the <strong>Dietary</strong> box and provide the appropriate *.rkg and *.res files</td>
</tr>
<tr>
<td>Residential</td>
<td>Place a “check” in the <strong>Residential</strong> checkbox and provide the appropriate *.rkg file</td>
</tr>
<tr>
<td>Tapwater (oral route only)</td>
<td>Place “checks” in the <strong>Dietary</strong> and <strong>Tapwater</strong> checkboxes and provide .rkg, .twc and NULL.RES files (*.rkg file does not contain any residential uses)</td>
</tr>
<tr>
<td>Tapwater (oral, dermal and inhalation routes)</td>
<td>Place “checks” in the <strong>Dietary</strong>, <strong>Residential</strong> and <strong>Tapwater</strong> checkboxes and provide the appropriate *.rkg, *.twc files and the NULL.RES file (*rkg file does not contain any residential uses)</td>
</tr>
<tr>
<td>Dietary and Residential</td>
<td>Place “checks” in the <strong>Dietary</strong> and <strong>Residential</strong> files and provide the appropriate *.rkg and *.res files</td>
</tr>
<tr>
<td>Diet and Tapwater</td>
<td>Place “checks” in the <strong>Dietary</strong> and <strong>Tapwater</strong> checkboxes and provide the appropriate *.rkg, *.res and *.twc files</td>
</tr>
<tr>
<td>Residential and Tapwater (with oral tapwater)</td>
<td>Place “checks” in the <strong>Dietary</strong>, <strong>Residential</strong> and <strong>Tapwater</strong> checkboxes and provide the appropriate *.rkg, *.twc files and the NULL.RES file</td>
</tr>
<tr>
<td>Residential and Tapwater (without oral tapwater)</td>
<td>Place “checks” in the <strong>Residential</strong> and <strong>Tapwater</strong> checkboxes and provide the appropriate *.rkg and *.twc files.</td>
</tr>
<tr>
<td>Diet, Residential and Tapwater</td>
<td>Place “checks” in the <strong>Dietary</strong>, <strong>Residential</strong> and <strong>Tapwater</strong> checkboxes and provide the appropriate *.rkg, *.twc and *.res file</td>
</tr>
</tbody>
</table>

**Exposure Analysis Files**

*LifeLine™ Version 4.4* provides estimates of exposure, dose, and risk. This version also allows you to generate up to five Exposure Analysis files, each of which provides additional detailed data on the characteristics of modeled persons, including their activities, diets and homes during each day of their lives. These files provide a rich record for the “audit trail” of your analysis and allow you to independently calculate the exposures and doses that the model estimates.

In general, the more exposure analysis files that you choose to generate, the more informative your results. These files are stored in a format (dBASE™) that is easy to process and examine outside the software, but requires additional time for formatting and storage. In addition, certain files must be created in order to run the **Summary Report** option.
Creating these files, however, will increase the length of time necessary to model a given number of individuals. This loss of analytical speed occurs because of the time required to save the files to the hard drive of your computer.

There are four Exposure Analysis files that provide data on the exposed individual:

- **LIVES.DBF** (two parts Demographics and Residential details)
- **DIET.DBF**
- **RACTIV.DBF** and
- **RESPUSE.DBF**

The two portions of the file LIVES.DBF can be created for any analysis performed with LifeLine™ Version 4.4. This file documents the physiological characteristics of each individual modeled, as well as the location and characteristics of the residences of those individuals. **This file must be created in order to create a Summary Report.**

The second file, DIET.DBF, can be created for analyses that include dietary sources. This file identifies the daily dietary record from the USDA’s 1989-91 Continuing Surveys of Food Intakes by Individuals (CSFII) used to simulate each individual’s dietary exposures on the days that are used to calculate the Random Day dose.

The last two files, RACTIV.DBF and RESPUSE.DBF can be created for analyses that include residential sources. The file RACTIV.DBF identifies the activity record from the National Human Activity Pattern Survey (NHAPS) used to simulate each individual’s residential exposures on the days that are used to calculate the “Random Day” dose.

The file RESPUSE.DBF identifies the pest pressure record from the National Home and Garden Pesticide use Survey (NHGPUS) used to simulate pesticide usage in each individual’s residence and the data extracted from that record used in the analysis.

**Population Mode and Size**

This allows you to define the size of the population to be modeled. Small populations (or single individuals) may be informative for identifying features of exposure that are highly correlated with age, or for “piloting” different sets of exposure assumptions as described above. Larger populations will produce more stable estimates of the range of exposures that might occur across the population.

In selecting population size, it is important to bear in mind that for each individual modeled, from 31,000 to more than 1,000,000 exposure estimates could be generated during the course of a lifetime of 85 years. The length of the time to perform the analysis may take from a few minutes to an overnight analysis, depending on the size of the population, the length of the life spans you wish to model and selected model options.
In addition, as the size of the population increases the size of the output files becomes very large. This size can be a problem for computers with smaller hard drives. In addition, the large size of the files can make accessing the files very cumbersome.

**TIP:**
The *LifeLine Model* is a computationally intensive system. In order to minimize the length of time to run the model you may wish to evaluate smaller sized populations when performing your initial analyses. Once you have determined the ages and seasons of interest, you may wish to model larger sized populations for the ages of interest.
If you are running a large number of individuals, only run the averaging periods, genders, and ages of interest.

**Range of Ages to Evaluate**
The *LifeLine Model* allows you to model the portion of the individuals’ lives you wish to model. If you wish to evaluate Carcinogenic Risk you must specify a value of 70 years or greater.

**TIP:**
The range of ages control can be used to limit the ages of the population considered in the analysis. For example if you are only interested in children then you can specify that the analysis only model the first 12 years of the individual’s lives.

**Dietary**
The second Tab controls how Dietary Records are selected for an individual. There are five components to this:
- Which dietary survey to use;
  - If the 1994-1996, 1998 CSFII is selected, which water consumption to use;
  - How often a new record is selected;
  - Whether database “weights” are used in selecting records and
  - The criteria used to match Dietary Records to demographic characteristics of the - individual being modeled.

**Dietary Survey**
In addition to being more recent, the 1994-1996, 1998 CSFII embodies substantial methodological changes from earlier CSFII rounds.
Water Consumption

There are multiple interim approaches for estimating domestic tapwater consumption from the 1994-1996, 1998 CSFII, three of which have been implemented in LifeLine™ Version 4.3 and Version 4.4:

- Fixed (by age) amounts {as in the case of 1989-1991},
- All municipal water not clearly from a non-household source such as a restaurant and
- Municipal water likely to reflect household sources.

Selection Frequency (Dietary)

This control allows you to specify how the daily dietary exposures are determined over a season. The current model provides two options. The **Every season of every year** option models an individual’s daily dietary exposure over an entire season using a single record. The **Daily** option models an individual’s dietary exposures over a season by selecting a different dietary record each day from a set of similar individuals.

While neither of these options is likely to be an accurate reflection of actual behavior, they provide a basis for limiting the uncertainty that arises from the use of short term data to model seasonal exposures.

Database Weights

For a variety of reasons, including non-response and incomplete response, the CSFII data do not fully match the intended target population. To compensate for this, weights were provided, so that the data in aggregate can be used to model this target population.

LifeLine™ Version 4.4 supports the use of CSFII weights (specifically, the three-year, three-day weights for the 1989-1991 CSFII and the four-year, two-day weights for 1994-1996, 1998), but it is generally inadvisable to do so.

Basis of Matching Dietary Data to Modeled Individuals

In LifeLine™ Version 4.4, each individual is modeled by selecting CSFII records from individuals with similar characteristics. The current version determines the group of similar individuals by selecting records from individuals with similar ages that were taken during the same season. These factors were found to be the critical determinants of dietary patterns in analyses of the CSFII data. Future versions of LifeLine™ will allow matching based on other criteria such as sex, region, or socioeconomic status. As the current version only selects the Dietary Group based on age and season, only one selection is allowed.
Residential

This tab allows you to choose how residential activity records are sampled and to review or modify default assumptions regarding applicator activity and room dimensions within a home.

Selection Frequency

This control allows you to specify how NHAPS records are used to determine daily residential exposures over a season. The current model provides two options. The Every season of every year option models an individual’s daily residential exposure over an entire season using a single pair of NHAPS records. This pair consists of a single weekday record and a single weekend day record. The single weekday record is used to model all of the weekdays in the season. The single weekend day record is applied to all weekend days. The Daily option models an individual’s residential exposures over a season by selecting a different NHAPS record each day from a set of similar individuals.

While neither of these options is optimal, they provide a basis for limiting the uncertainty that arises from the use of short-term data to model seasonal exposures. Please refer to the Technical Manual for an additional discussion of this issue.

Relationship of Activity to Application

Any activity in a home on the day when a pesticide application occurs may occur either before or after that application, with significant consequences for the exposures that would be predicted to result from that activity. In addition, the product may be applied by someone other than the person being modeled.

The first window allows you to specify a probability that a reported activity on the day of application occurred before or after application. The default value is 0.5 (equally likely that the activity preceded or followed application). This value may be set anywhere between 0 (the activity preceded the application - application followed the activity) and 1.0 (the application preceded the activity).

The second and third options address the difference in sex-specific patterns of pesticide use. Data from NHGPUS suggest that females are more likely to be applicators for residential pesticides used indoors, while males are more likely to be applicators for residential pesticides used outdoors. In the second window, you can specify the probability that the applicator indoors was female (the default value is 0.7). If this value is set to 1.0, males are assumed never to be the applicator for indoor applications; if it is set to 0, males are always the applicators. The third window offers a parallel choice for outdoor applications. The default in this case is a probability of 0.7 that the male will be the applicator outside. If it is set to 0, only females will be assumed to be applicators outside, etc.
Room and Hallway Dimensions

Available databases allow one to address the size of a home and the rooms in it, but not the relative dimensions of those rooms. The system automatically assigns relative sizes to different rooms (proportions of total floor space). This section allows you to specify the general assumptions regarding room dimensions and hallway dimensions. In general, this will be of greatest importance in evaluating crack and crevice pesticide use. The longer and narrower a room or hallway, the greater is its ratio of perimeter to floor area. The default dimensions (width: length) for rooms are 2:3, while for hallways they are 1:10.

Time Spent Playing with Pets

Interaction with pets is not tracked in the National Activity Pattern Survey. As a result, the user must enter a value for this duration. This number is only used for the estimation of exposure to EUPEs applied to pets.

Averaging Period / Toxic Hazard

The final Tab allows you to enter your choices for averaging period. This Tab also allows you to review the toxicity data that will be used to assess risk for each selected averaging time. As noted briefly above, the system supports evaluation of different exposure durations. These work as follows. If you have selected a 7-day and a 30-day averaging period then on any given day, the system generates three different exposure estimates. Thus, for oral exposure, the system would determine the:

- Oral exposure on that day (the 1-day exposure);
- Average oral exposure for that day and the preceding six days (the 7-day average exposure) and
- Average oral exposure for that day and the preceding 29 days (the 30-day average exposure).

Similar estimates would be generated for residential, diet, tapwater, and aggregate exposures.

This option allows the exposure evaluation (and subsequent risk characterization) to be freed from the arbitrary distinction into “acute,” “subchronic” and “chronic” categories, and to be matched to the actual time-dependence of toxic effects that are seen with the particular AI.

As an aid to this matching, the bottom of this Tab contains a display of the toxic hazard data that are available from the currently selected Risk Group file. For each of the three possible types of toxic hazard (short, intermediate and long-term), the range of relevant exposure averaging periods is displayed, as is the availability of route-specific and/or
systemic toxicity data. The display indicates whether data are sufficient only for an MOE analysis or for evaluating percent of the Reference Dose (RfD).\textsuperscript{10}

You may also choose to evaluate an averaging period where there are no available toxicity data. In this event, you will be able to evaluate exposures and/or doses for this averaging period, but you will not be able to assess risks.

**Data Files Requested**

If you have included dietary exposures, the system requires you to specify the name of the *.res file containing food residues before you continue. Select the appropriate file, based upon the work you have done with the *Food Residue Translator* system.

If you have included residential exposures, the system requires you to specify the name of the *.acd file containing quantitative activity descriptions before you continue. If you do not specify a file that you have constructed with *Activity Description*, the system will give you a warning message, and then will use the default values supplied with the system.

If you have included tapwater exposures, the system requires you to specify the name of the *.twc file containing distributions of tapwater concentrations of your AI before you continue.

**Button 2. Population Characteristics**

Once you have defined your analysis, you can define the modeled population based on their permanent demographic features. You may limit your analysis to a specific: Sex, Race, Ethnicity, Socioeconomic status (income quartile),\textsuperscript{11} or any combination of these factors.

LifeLine\textsuperscript{TM} Version 4.4 does not allow for a specification of the modeled population based on factors that change over an individual’s life, such as region, setting, housing type, water supply, season, day of the week or the individual’s age. The impact of these factors; however, can be investigated after the model is run. Using the *Risk-Dose-Exposure Report* program and by analyzing the output files it is possible to determine the impact of each of these factors alone or in combination with one another.

\textsuperscript{10} The display does not indicate the availability of data on carcinogenic hazard, as these are not relevant to the selection of exposure averaging periods, but rather are always applied to Lifetime Average Daily Dose.

\textsuperscript{11} Technically, this last is not a permanent characteristic of an individual. In practical terms, it tends to remain relatively stable for an individual’s entire lifetime. Future versions of LifeLine\textsuperscript{TM} may include the changes in socioeconomic status.
After you have described the population, the system loads the appropriate data files for the analysis and population that you have described (e.g., data on growth, mortality, residential characteristics, etc.)

**Button 3. Running the Simulation**

After population is defined, the **3. Start Analysis** button becomes active. Clicking on this button begins the generation of individual life exposure histories, which continues until all daily exposures have been modeled for the whole population.

**TIP:**
The *LifeLine Model* is a computationally intensive system. You should strongly consider not running any other programs during the analysis of large populations if you have an older computer or limited amounts of RAM.

While the program is running, the program displays selected characteristics of each modeled individual. A counter displays the day being modeled (and life year) of each individual, and a second counter displays the total number of person-days that have been modeled thus far. A progress bar indicates the percentage of the total number of specified person-days that has been modeled.

When the last day of the last modeled individual has been assessed, the system displays the message:

**Analysis Completed. Ready to generate report files.**

What the *LifeLine Model* has done during its analysis is simulate the exposure histories of each individual. The exposure estimates from this have been saved as a dBASE file in a temporary file location. The file is entitled EXPOSURE.DBF and the data in it can be analyzed and extracted using spreadsheet or database software. The program has also created the Exposure Analysis files specified in the analysis preferences.

The **4. View Analysis Results** and **5. Generate Reports** buttons become activated at this point, as does the menu option **Lives/Move exposure analysis files to a folder of your choice.**

It is recommended that you save the model’s output for later analysis (see *Viewing and Saving Outputs* below). The reason for this is that when the program is re-run all of the Exposure Analysis files from the previous model runs will be lost (see above).

**4.9.4 Button 4. View Analysis Results**

This button is optional and may be skipped. The button presents the contents of the Exposure Analysis files for:

- Each individual (permanent characteristics) and
• Each year in an individual’s life.
  o Body dimensions (annual);
  o Residence characteristics (annual);
  o Dietary data selected (from the random day) and
  o Activity records selected (from the random day).

The completeness of this display depends upon the number of Exposure Analysis files that have been generated. If none of these files were created, this window will appear blank and a warning will appear.

This display does not contain any information about exposures. Rather, it presents data that were used to calculate those exposures. You must use button 5. Generate Reports option to view the exposure estimates or use other software to analyze the output files of the program.

Exposure Analysis files may be extremely useful in determining the factors that are driving exposures or risks. Because they are overwritten with each new analysis, provision has been made for saving a copy in a folder you designate. Use the Lives/Move exposure analysis files to a folder of your choice option on the menu bar to do this. You will be prompted with the name of a text file to be stored in \My Documents (you may want to change to another folder or create one). This text file contains the current date and time for future reference. Use any filename you wish and click on Save. (If you keep the extension .txt, it will facilitate examining the file with Notepad or a similar program). Not only will the time stamp file be saved but all Exposure Analysis files created last will also be copied from the system folder to the chosen folder. A progress bar will display the status of the copying procedure.

4.9.5  Button 5. Generating and Viewing Reports

By clicking on the Final button, 5. Generate Reports, you call up a separate program for post-hoc analysis, Risk-Dose-Exposure Reports.

4.10  Model Outputs

The contents of EXPOSURE.DBF are the collected exposure histories of a population. Where the population is has been carefully designed to be a statistical representation of the population you defined in the Analysis Preferences and Population Characteristics steps of the LifeLine Model program. One drawback to this approach is size of EXPOSURE.DBF. The size of the file can easily exceed 15 gigabytes for larger populations. In order to avoid generating files that could overload older computers and would be difficult to access on newer computers because of their size, LifeLine™ Version 4.4 calculates but does not save the dose estimates for each day. Instead, the model saves the average exposure for each year and season, the maximum dose that occurs on any day in a season for each year and season, and the doses that occur on a randomly selected day from the season and year. This reduction of the data saved results in more than a 30-fold reduction in the size of EXPOSURE.DBF.
4.11 Analyzing Your Results Using the Risk-dose-exposure reports (RDER) program (Drill Down)

The Risk-Dose-Exposure Report (RDER) program can be accessed in two ways. It is represented by a button on the LifeLine Model main interface, button 5. Generate Report and it may be called directly from the windows Program menu Risk-Dose-Exposure Reports in the same program group as other system files.

4.11.1 Data (and Specific Files) Required

The RDER program creates “views” of an extremely large file of exposure estimates produced by the LifeLine Model (EXPOSURE.DBF). This latter file, which often runs to many megabytes, contains seasonal summary data for every exposure metric for every individual. The entire purpose of the RDER program is to extract portions of this massive file and organize the data into more familiar (and useful) presentations. These presentations can be expressed as graphs or as tables. The graphs and table can in turn be exported to other programs. Unless EXPOSURE.DBF has been created, however, the RDER program will not function.

In Version 4.3 and above the RDER program also contains a new function the Summary Report. The Summary Report is discussed in Chapter 4.12 of this Manual.

The contents of EXPOSURE.DBF are the collected exposure histories of a population. Where the population is has been carefully designed to be a statistical representation of the population you defined in the Analysis Preferences and Population Characteristics steps of the LifeLine Model program. These population exposure histories can be viewed as a series of “exposure surfaces,” in which the x-dimension is age, the y-dimension is the individual, and the z-dimension is exposure. A separate surface would exist for each exposure metric (e.g., seasonal average daily oral exposure, random day dietary exposure, seasonal maximum 7-day exposure from residential uses, etc.) you defined in the Analysis Preferences step. Depending upon the availability of data on toxic hazards in the Risk Group file, an even larger number of surfaces may exist for measures of risk (e.g., both Margin of Exposure (MOE) and percent Reference Dose (RfD) presentations of most exposure metrics).
The RDER program allows you to summarize these data, taking either a longitudinal perspective (individual or population values over time), or examining the pattern of exposures in the population at a particular age and season.

4.11.2 Last-Generated Exposure File (Default)

When you start RDER, you can immediately create a view of the EXPOSURE.DBF file that was created by the last run of the LifeLine Model. The controls to generate these views will apply to the results of the last run of the model, unless you have specified a previously saved file as the starting point for your views.

4.11.3 Previously Saved Reports

If you have saved a report (i.e., a file with extension *.rtl) created by this program (see below), you may use the File/Open option from the menu bar or click on the open file folder in the Toolbar to open the file for review, printing or (if the source files still exist, see Exposure Files and the Browse Function) for further analysis.

4.11.4 Exposure Files and the Browse Function

The default location for EXPOSURE.DBF is the \RTL directory, where the results of the most recent model run with the LifeLine Model will be located. It is possible, however, to utilize the results of previous runs of the LifeLine Model, if you have used the option (described in the LifeLine Model program, see Viewing and Saving Outputs, Section C.5.) to copy them to another location. The Select exposure analysis folder button at the bottom of the left panel of the RDER program allows you to select the location of the files that you will use to generate your views. This feature is also important if you have saved a Report file from the RDER program (*.rtl file; see below) and wish to recall it for further analysis.

4.11.5 The Display

The program presents a “split window.” On the left side of the display is a set of controls in a tabbed interface that allows you to describe the view (a table or graph) that you want to create. On the right side is a window that displays the table or graph that you have created. The Toolbar and menu bar contain controls that define the view.

A separate Toolbar is activated whenever a graph is displayed, and shown in the graph window. This toolbar allows you to control the appearance of the graph. For example, you may select linear or logarithmic spacing of axes, display of symbols, trend lines or both, etc.
Because the generation of views is now interactive, there is no permanent copy of any view you generate unless you explicitly save or export the view that you have generated. You need to generate permanent files only for those views that you consider important, but you must take affirmative action to make those files.

Basic Views

The views that are generated by this program (whether tabular or graphical) can each be viewed as a cell in a table with four rows and four columns, as shown in the following table. Each row is a view type, and each column is a set of data series to include. Every view can be presented either as a table or as a graph.

<table>
<thead>
<tr>
<th>View Types</th>
<th>Data Series</th>
<th>Total vs. Routes</th>
<th>Total vs. Source Terms</th>
<th>Average vs. Max.</th>
<th>Compare Durations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals Over Time</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Population–Typical Over Time</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Population at Specific Time</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Cancer (Lifetime Average)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

As discussed above, the first view type slices the population exposure surfaces described in EXPOSURE.DBF parallel with the age axis, resulting in \( n \) different exposure histories for the \( n \) individuals modeled. The third option slices the surfaces perpendicular to the age axis. This results in up to 340 different distributions (85 years by 4 seasons) of doses in the population. The second option integrates the data perpendicular to the age axis. (The cancer option inherently averages over time).

View Types

When viewing individuals over time, the view contains the data from all seasons from the start and end ages selected by you. This view, which is the most detailed, allows you to “scroll through” a series of individual exposure histories, noting how each individual’s pattern of exposures changes over time.

When viewing population-typical values over time, the system first integrates the population at each point in time to produce a representative value (e.g., population mean). The view then displays the changes in that value as a function of age and season.

When viewing the population at Time X, the system displays the individual values for every member of the modeled population at an age and season (e.g., winter of the 45th year of life) that you select. The model also allows the modeling of the entire year.
When viewing cancer [Lifetime Average Daily Dose (LADD)] or corresponding risk, the system first calculates the Lifetime Average Daily Dose for every individual. It displays either that dose or the corresponding cancer risk. The Risk option is only applicable when fixed lifetimes of at least 70 years have been evaluated in the exposure assessment.

Data Series

For each of the three basic view types, you have the choice of the same four basic data comparisons:

- Comparing route-specific (oral, inhalation, dermal) exposures to total exposure for a particular time frame and exposure type (e.g., seasonal average one-day exposure);
- Comparing source-specific (food, tapwater, residential) exposures to total exposure for a particular time frame and exposure type (e.g., seasonal average one-day exposure);
- Comparing the average and maximum values seen for a particular duration and route or source of exposure (e.g., one-day oral exposures); and
- Comparing exposure durations for a particular exposure type (e.g., seasonal average oral exposure).

For the first three options, either exposure/dose or risk metrics may be employed. Because the last option would in many cases involve the comparison of qualitatively different risks only exposure views are supported.

Multiple Views

For any one of these twelve basic varieties of view, numerous specific instances might be of interest. For example, if we consider only the third view type (population cross-section) for route-specific comparisons, there are 340 possible combinations of age and season, up to five possible exposure durations (1-day, 7-day, etc.) and either seasonal averages or seasonal maxima that could be selected, for a total of more than 2,700 views of the same basic type (more if both exposure and risk are considered). The system allows you to generate, view and save or export as many of each type of view as desired. Selecting View Options (Controls on the left side of the Interface).

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12 This presents slightly different data when population values are being presented than when individual values are presented. In the latter case, you will see either the maximum seasonal value for each individual, or the average seasonal value for each individual. In the former case, you will see either the maximum value for the population or the average value for the population, but each individual contribution to that population value is the average seasonal value for the person.
Selecting the Location of Exposure and Exposure Analysis Files for Report Generation

The default setting for this program is to base views on the EXPOSURE.DBF from the most recent analysis performed with the LifeLine Model program [see Last-Generated Exposure File (default)]. These files will be saved in the \RTL directory, and will have overwitten any previous versions of those files in that directory.

The LifeLine Model allows you to copy these files to a different directory, so that running new analyses will not destroy the results of previous analyses (see Exposure Files and the Browse Function). If you have saved an analysis, you may use either the saved analysis or the results from the most recent analysis performed with the LifeLine Model program (or both) to generate views.

To change the EXPOSURE.DBF and the Exposure Analysis files used to generate views, click on the Select Exposure Analysis Folder button at the bottom of the View
Generation Options window (left side of the screen). Immediately above this is a window showing the current location being used for these files.

When you click on the Select Exposure Analysis Folder button, you call up a standard window that displays the contents of the currently selected directory. A drop-list allows you to navigate between folders until you find the one where the Exposure Analysis files of choice reside.

By selecting a directory that has your saved exposure and Exposure Analysis files and clicking on the Open button, you will change the location used by the program to generate views. The system will warn you if you attempt to select a directory that does not contain such files, and will not change the model output directory.

**NOTE:**

If you are displaying a view, and change the directory for output files, and the system either cannot find Exposure Analysis files in the specified directory or finds files that do not correspond to the Report file, the button labeled Create Report with Current Options is replaced by a warning that the displayed report was not based upon the files contained in the new directory. To generate a report, you must either use the Select Exposure Analysis Folder button to return to the appropriate directory, or create a new file (by clicking on the blank sheet in the Toolbar or choosing File/New from the menu bar.)

You can access additional information about the Exposure Analysis files being used through the View/Exposure analysis information menu option.

Basic View Types

The RDER program interface uses four tabs to distinguish between the three basic view types described above (individuals over time, population (summary over time), (population at a) specific time (age and season), or cancer). These are located near the bottom of the View Generation Options window, just above the window that displays the location of the model output files. You select one of the three View types by clicking on the corresponding tab.

Overall View Options

The View options offered by the tab for each of the three view types are fundamentally very similar. The most options are offered in the first tab, Individual Exposure Histories Over Time. The other view types have fewer options. The following discussion will discuss the selection of options for the first view, noting differences in the other view types where relevant.

Generating a Table or Graph
At the top right of the View Generation Options window is a box labeled View, containing radio buttons Data or Graph. The former will lead to a tabular display, the latter to a graphical display of the same data. The same effect can be produced by clicking on the table and graph icons in the Toolbar, or by choosing View/Spreadsheet or View/Graph from the menu bar.

**IMMEDIATE RESPONSE:**
Unlike the other selections, these radio buttons will automatically toggle the display between a table and graph. To activate other changes in the report, you must click on the Create an Exposure Analysis… button after making your selections.

**Basic View Options**

Once you have selected one of the three basic types of view (the tabs), you must choose one of the four basic view options (source contributions, route contributions, average vs. maximum and comparison of averaging periods). The other options that you have are affected by the choice you make here.
**REMEMBER:**
When population data are displayed across time, *Average* refers to the mean population value of the seasonal average data. *Maximum* refers to the highest value seen in the population of the data for seasonal average for each individual.

When individual data are shown, the average is the individual’s average value for the season, and the maximum is the highest value seen for that individual in that season.

**Data Item**
This set of radio buttons allows you to switch between *exposure/dose views* and *risk views* (either MOE or Percent RfD in the first three tabs, and excess risk in the *Cancer* Tab). The particular Risk options that are functional will depend upon the availability of corresponding toxic hazard data. If data are not available, the options will be grayed out.

For example, if you have no intermediate or long-term toxicity data, and want to view an exposure-averaging period that is longer than the maximum for short-term toxic hazard data, you will only be able to create exposure views, and not risk views. Similarly, if you have only specified No Observed Adverse Effect Level (NOAELs) (or similar) for a particular type of toxicity, you will be able to generate an MOE analysis, but not a percent RfD analysis.

If you have full toxic hazard data for any route (but not all), you can display the corresponding risk report for either the all sources or all routes, even though these may be incomplete. Similarly, if you are considering a single source term that has multiple exposure routes associated with it, you may evaluate risks that are supported for any relevant route. If, however, you are viewing a single route (for example, in the *Average vs. Maximum* option), only the analyses supported by hazard data for that route will be available.

**NOTE:**
LifeLine™ Version 4.4 determines aggregate risk based on the systemic (absorbed) dose that occurs as the result of multiple routes of exposure to one individual on one day.

A second type of risk aggregation seeks to sum the risk that occurs from both systemic and route-specific toxicity (portal effects). An example of such aggregation of risk might include skin irritation from dermal exposure, loss of lung capacity from inhalation, and kidney effects resulting from oral...
exposure. LifeLine™ Version 4.4 does not attempt to aggregate such risks. Doing so requires very strong policy assumptions that are best addressed in another context. The system does produce outputs that can be used in such assessments, but does not automate them.

View Time Frame
This option is independent of the basic view option. For the two longitudinal views, it specifies the starting and ending age and season. For the cross-section, or interindividual variation, of the population (Population Exposure Profile at a Point in Time), it specifies the age and season for which the population data are displayed.

Choices for Each View Option

Route Contributions
This option generates a comparison of Total exposure to oral, inhalation and dermal exposure for any selected metric.

When this option is selected, you must choose:
- The exposure duration periods of the data (i.e., daily, or any longer window that you may have specified in setting up your analysis); or
- Whether to display seasonal average data or the seasonal maximum value.

Note: For views dealing with the population over time, all displays involve seasonal averages, rather than seasonal maximum.

CAUTION:
Seasonal maximum values are calculated independently for each Route, Source and Exposure Duration window. When running a comparison of routes or sources, for example, you should be aware that the maximum value for a particular route or source may represent a different day than the maximum value of another route or source, or from the day the total exposure maximum occurs.

CAUTION:
It is very important to bear in mind that the total, oral, inhalation and dermal route risks reflect independent estimates of toxic hazard, and therefore may not be directly comparable. For example, a dermal risk may represent mild skin irritation while an oral or total risk is based on systemic liver effects.
Source Contributions

This option generates a comparison of Total exposure to food, tapwater and residential exposure for any selected metric.

When this option is selected, the subsidiary options are the same as those for route contribution comparisons. You must choose:

- The exposure duration period for which to display data (i.e., daily, or any longer window that you may have specified in setting up your analysis) and / or
- Whether to display seasonal average data or the seasonal maximum value (see notes and warnings above).

Averages of Seasonal Average vs. Maximum of Seasonal Averages

This option addresses the comparison of the random day, seasonal average values and maximum seasonal values for a particular metric. Accordingly, the choice of displaying average or maximum values is no longer offered (both are displayed). You must, however, specify:

- The exposure duration period for which to display data (i.e., daily, or any longer window that you may have specified in setting up your analysis) and
- The particular exposure metric for which you wish to compare seasonal average and maximum seasonal values: total, oral, inhalation, dermal, food, tapwater and residential.
NOTE:
When looking at the entire population at a particular point in time, selecting this basic view option activates a checkbox labeled **Create subsidiary report file**. If you check this option, the system will automatically capture (from the Exposure Analysis files) a description of the diet and activities that were recorded on the day on which the selected metric was recorded, for the individual with the highest average value and for the individual with the highest maximum value:

- CSFII records for the individuals (CSFII identifier, food names and amounts consumed)
- NHAPS records (weekday or weekend)
- Residence description

These data are added to the view spreadsheet that is created (considerably expanding the size of that spreadsheet).

If you elected not to generate the corresponding Exposure Analysis file(s), these additional data are not available for incorporation into your report.

You must choose:

- The exposure duration period for which to display data (i.e., daily, or any longer window that you may have specified in setting up your analysis) and
- The particular exposure metric for which you wish to compare seasonal average and maximum seasonal values: total, oral, inhalation, dermal, food, tapwater and residential.

**All Exposure Duration Periods**

This option compares the estimates of dose for different averaging periods for a specific age and season. In generating views of this type, you must specify:

- The particular exposure metric for which you wish to compare seasonal average and maximum seasonal values: total, oral, inhalation, dermal, food, tapwater and residential and
- Whether to display seasonal average data or the seasonal maximum value (see notes and warnings above).
This option is not relevant when considering population values over time.

As noted above, risk metrics are not supported for this view, because it would involve a quantitative comparison of qualitatively different risks.

### 4.11.6 Displaying a View

Once you have specified the options for your next view, you can click on the button labeled **Create an Exposure Analysis View with Current Options**, located at the top left of the View Generation Options window.

When you do so, the system will replace the display on the right with a new view reflecting the options that you have selected.

**NOTE:**
It is important to bear in mind that the **Print** and **Export** commands described below apply only to the currently displayed graph or table. In addition, you must actually click on the graph or one of the cells in the table in order to print or export.

**General Viewing Controls**

You can use the radio buttons in the View Generation Options window, the graph and spreadsheets in the Toolbar

![Icon for View/Spreadsheet](image)

and the **View/Spreadsheet** and **View/Graph** options from the menu bar to switch between graphical and spreadsheet views of your selected view.

Some views also entail multiple views. For example, when viewing individuals over time, there is a separate graph and spreadsheet for each individual. When viewing source contributions, route contributions, or different averaging periods for a population, there is a separate view for the average and maximum values for the population. The **Next/Previous** function in the **Report** menu option allows you to change between these multiple displays in a view.

The Toolbar contains two buttons with arrowheads:

![Previous](image) pointing left (Previous) and ![Next](image) pointing right (Next)

There are also **/Next** and **/Previous** options under **View** on the menu bar. To activate these options, you must click on the graph or spreadsheet being displayed. In addition,
you can display the view for a specific individual with the Report/Go to person menu option. This is only applicable to the Individual Over Time view.

Spreadsheet Viewing Controls

When a spreadsheet is being displayed, you have the option of changing the font, font style (e.g., bold, italic), and font size. To do so, click on the spreadsheet, then select Spreadsheet/Font from the menu bar. Available fonts, styles and sizes are displayed in a dialog box.

For spreadsheets that contain the data for a population at a particular point in time, you also have the option of sorting data (on an ascending or descending basis) based on total exposure (or its corresponding risk estimate). This option only applies to views of exposure or risk by route or source (i.e., those views that include total exposure and some other metric of exposure).

This option, called by clicking the A-Z and Z-A buttons on the Toolbar

will affect the display of both the spreadsheet and its associated graph. The sorting of the individual’s records will be performed using the total dose or the dose that appears in the right most column of the table. If you wish to sort based on some other dose, open the table view, highlight the column by clicking the top cell of the column (the entire column will be highlighted) and perform the sorting.

Graph Viewing Controls

For many purposes, you may wish to change the appearance (but not the content) of a view graph. A special Toolbar is displayed with the graph that allows you to do this. The available options are described here. In some cases, calling one option will also provide access to a set of tabs that address other options as well. In other cases, only the specific Toolbar button provides access to the option.

A brief description of each Toolbar icon is presented here. If you want to be sure what a button does, place the cursor arrow over it. After about one second, the description of the button pops up.

Graph Style

The Graph button
controls the most fundamental aspects of graph appearance:

- Whether to show data using symbols, lines and or “sticks” (a vertical line from the data value to the x-axis). While the default is to use lines, many users prefer to mark individual data points with symbols.
- Whether to use linear or logarithmic coordinates for the graph axes. Because exposure and risk values may vary over several orders of magnitude, the logarithmic presentation of the y-axis can be very informative. Logarithmic spacing of the x-axis (which either represents time or persons) does not make any particular sense.

Showing / Hiding Data

For views of exposure by route and by source, the default display includes total exposure as well. In some cases, this can obscure the comparison of contributions by different sources or routes. The button marked with a spreadsheet allows you to toggle these values on or off.

This button also allows you to turn off gridlines (that continue the y-axis tick marks across the full width of the graph).

Showing / Hiding Gridlines (Axis)

This button, marked with a numbered grid, allows you to turn off gridlines (that continue the y-axis tick marks across the full width of the graph).

It also allows you to toggle the display of total exposure on or off.

Fonts

This button, marked with a lowercase and uppercase A,
Markers

This button, marked with a pale green x,

allows you to change the size, color and shape of any data marker that you are using.

First, use the little graph with the black pointer arrow to select the marker that you wish to modify. The number of the selected marker set will be displayed below the graph.

Then you may change the color, pattern, symbol and size of the selected marker. If you have lines displayed (see above), you may also make them either thick or patterned. The **Reset All** button at the top right of the control Tab affects color, pattern and shape, but not size.

Background

This button (yellow graph)

allows you to apply styles (colors, backgrounds, borders and shadow effects) to the areas used for titles, the legend and the graph. You may also specify a background color (or bitmap) for the entire graph window.

Investigating Data Points in a Graph

If you are curious about a particular value in the graph, you may click on it. The nature of the point (e.g., the route, source, etc.) is displayed, along with the x- and y-values for the point, in a pop-up box. If you want to hide this box, switch to the table view and then back again, or click on the control panel on the left side of the display.

4.11.7 Printing a View

Both tables and graphs may be printed directly, either by clicking on the Printer in the Toolbar

or by selecting **File/Print** from the menu bar. These commands apply to whatever graph or table is currently being displayed. **Print Preview** will first prompt you with a menu for the printer to which the view will be directed, and then display the view as it would appear under the settings currently applied to that printer.
Print Setup (also under File) controls the basic specifications of your printer.

4.11.8 Saving a Report or Exporting a View

There are two different ways to save any report that you have created. The Save and Save As options save your report in an internal format (an *.rtl report), which can later be opened with the program. Saving an *.rtl file will also save the folder name, date and time information for the files used to create the report, so that further views can be created (assuming that these underlying files have not been overwritten or otherwise destroyed; the system provides a warning for this scenario). You may also export the files in formats suitable for use by external software systems.

Saving an RTL File

To save your current report in the format used internally by LifeLine™ Version 4.4, either click on the diskette in the Toolbar

or choose File/Save or File/Save as from the menu bar. You will be shown a dialog box that prompts you for the name of the file (the file type is fixed as *.rtl), and allows you to select the directory in which to save the file (the default is \RTL\WORKSPACE). This option saves both the spreadsheet and graph forms of the file. Files saved in this manner can be displayed again using the folder

or the File/Open option in the program.

The system provides a warning about the link between the view in the .rtl file and the underlying Exposure Analysis files.

Exporting View Files

The Save and Save As functions save your report (and pointers to its source data) in an internal format that provides for efficient plotting. For other purposes (e.g., creating formal reports), it may be more useful to save these data in a common exchange format. LifeLine™ Version 4.4 supports the export of both the graphical and spreadsheet displays produced by RDER. Export of spreadsheets and graphs is, however, independent. Saving a graph will not save the corresponding spreadsheet, nor vice versa.
If a graph is being displayed (and is selected), the **File/Export Graph** option on the menu bar is active. If a spreadsheet is being displayed (and is selected), the **File/Export Spreadsheet** option is active.

### Exporting Graphs

Graphs (but not tables) may be exported as picture files (Windows metafiles, bitmaps or JPEG files) for incorporation into documents, later printing, etc. To export a graph, choose **File/Export graph** from the menu bar. This will call up a window that will prompt you to supply a name for the file and to select which of the three export formats you wish. It will also display all files of that type in the `\HRI\RTL\Workspace` directory. As in the case of file opening, you may change the directory or drive for exporting.

### 4.11.9 Exporting Spreadsheets

Spreadsheets (but not graphs) may be exported as an Excel™ spreadsheet or dBASE™ IV format file. To export a spreadsheet, choose **File/Export Spreadsheet** from the menu bar. Clicking on this option calls up a dialog that allows you to select the directory in which the view should be saved (the default is the `\RTL\Workspace` directory), to specify a name for the file, and to choose either Excel or dBASE format.

It is also possible to export data to Excel worksheets by simply cutting and pasting the cells.

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13 If the desired export option is not active but the correct display is showing, click on the spreadsheet or graph to activate the display.
4.12 SUMMARY REPORT for Dietary Exposures

LifeLine™ Version 4.4 software has a function that enables generation of a Summary Report for Dietary Exposure. The format of this report was developed by The LifeLine Group with input by EPA staff and captures the information most often used in EPA regulatory decision making. In addition, the report provides information on factors such as:

- Variation in chronic exposures and risks;
- Variation in lifetime average daily exposures and cancer risks;
- Seasonal variation in exposures from diet and tapwater and
- Information on the maximum and average daily exposures.

4.12.1 Description of the Summary Report

The summary report function automatically extracts the data from the output files (EXPOSURE.DBF, LIVES.DBF and other output files) of a LifeLine™ Version 4.4 model run and presents the exposure estimates using the following traditional age and gender based subpopulations:

1. General U.S. Population;
2. All Infants (<1 year);
3. Children 1-2 years old;
4. Children 3-5 years old;
5. Children 6-12 years old;
6. Youth 13-19 years old;
7. Adults 20-49 years old;
8. Adults 50+ years old and

Separate tables for the acute and chronic toxicity data are generated.

The summary report includes detailed documentation of all of the assumptions that were entered into the model run that produced the data including:

- Date of model run
- Version of LifeLine™ used
- ID portion of user’s password
- Name of Input files and dates and time they were last modified
- Number of individuals simulated: 1-40,000
- Age range simulated: 0 to 85
- Sources considered:
  - Food (Yes/No)
  - Water (Yes/No)
  - Sex: Males only, Females Only, Both
  - Ethnicity: Hispanic, Non Hispanic
  - Race: White, Black or Other
• SES quartiles: 1, 2, 3, 4 or all
• CSFII survey year: 1987-89 or 1994-6
• Dietary drawing frequency: Daily or Seasonally
• Were CSFII weights used: Yes/No

4.12.2 Creating a Summary Report within the Risk Dose Exposure Reports Module

The summary report is created by extracting data from EXPOSURE.DBF, LIVES.DBF and other output files and converting it to an Access™ database for the selected subpopulations. The Access database is then used to create the desired tables and graphs. The tables and graphs are automatically formatted into a report. The various pages of the report are presented in a series of tabbed windows that you can browse. The entire report can then be printed or saved in a variety of formats including Microsoft Word™, Rich Text Format™, Adobe Acrobat™ and Microsoft Excel™. The Access database can also be saved for addition analyses.

The creation of the summary report within this module can be done at any time after the completion of the model run data. If a Summary Report was run previously during the initial model run in Deliver, the report may be viewed in the Risk Dose Exposure Reports Module without the need to perform the calculations a second time. See 4.12.3 for more information on creating a Summary Report in the Deliver application.

To create the summary report, perform the following steps:

Step 1
Perform a model run in **LifeLine** Version 4.4 and save the outputs. See the **Users Manual** for instructions on how to save output files for future use.
**Note:** The LIVES.DBF output files must be created in order for the creation of the Summary Report.

Step 2
Open the **Risk Dose Exposure Reports** (RDER) module. The left side of the window includes a new button labeled **Summary Report**. Selecting this button opens the Summary Report Parameters window.

Step 3
Select one or more of the populations, then select the Exposure Duration of interest. You can also provide a name for the model run (e.g. Test of Carbofuran Residue Data Set). The length of the name can be up to 75 characters. In addition, a brief report description (up to 255 characters) can be entered in the window provided. The name and report description will be printed as part of the Summary Report.
Step 4
Once the populations and duration are selected, click on the Generate button. An hourglass will appear for a period from a few minutes to more than 30 minutes and then the Summary Report Parameters window will close. The duration of time is a function of the speed of your computer, the amount of memory and whether you are running other programs. Once the hourglass disappears, a bar will appear and will show the progress of the program in completing the software. If you have simulated exposures for a large number of individuals (10,000) and for periods of their entire life (0-85 years); the program may require two hours or more to create the Summary Report.

**Warning:**
Once the Summary Report is created, LifeLine™ Version 4.4 will automatically open the report. Do not try to create two reports at the same time.

In addition, please make sure that only one copy of RDER is open at any time. Having two copies of RDER in operation can cause problems when they are reading different copies of exposure.dbf.

### 4.12.3 Creating a Summary Report within Deliver

LifeLine™ Version 4.4 has the ability to process the Summary Report within the same process as the Deliver model run. By placing these two very time-intensive processes subsequent to each other and without interruption, much larger LifeLine runs can be performed that might take 6-8 hours of processing time on an average computer. In order for the Summary Report to process in Deliver, it must be set up in advance of the model run. This is done by the following steps:

1. In the Analysis Preferences dialog, select the Summary Report tab.
2. Click the Enable Summary Report check box. Once this is clicked, the rest of the screen will be available for user input.

3. Select the populations that are to be included in the Summary Report. The Select All button will automatically select all the possible age groupings.

4. Select the Exposure Duration that should be used for the Summary Report calculations. To add an additional Exposure Duration, click the Averaging Period / Toxic Hazard tab. From here, 4 additional averaging periods may be selected. Once these have been set, go back to the Summary Report tab and the new exposure durations will be added to the drop down box. Only one exposure duration may be processed within a Summary Report at a time. If additional Summary Reports are desired using different exposure durations, those Summary Reports can be generated against the data later using the Risk Dose Exposure Reports Module later.

5. Currently, the only Dose supported in the Summary Report is Oral. Additional doses may be added at a later date.

6. Select an appropriate title and description for the report. These will appear once the report is generated.

7. Once the report has been set up, you may click Ok or adjust additional Analysis Preferences.

The Deliver will run as it normally does, but upon completion of processing all the lives, it will automatically begin to process the Summary Report. There may be a 3-5 minute pause between when the Deliver run finishes and the Summary Report begins. While the Summary Report processes, there will be very little user feedback. It is important to let this process complete and not interrupt it. On very large runs and on slower computers, the Summary Report can sometimes take longer then the model run itself. On a slower computer, a Not Responding message could be reported by the operating system. This simply means that the program is engaged in a large calculation and unable to report progress to the operating system. Thus, a not responding message is generated and should be ignored. Once the Summary Report completes, the report will open and be displayed. If the report is closed, it can be reopened without reprocessing all the data by going back into Analysis Preferences in Deliver and clicking View Report, or by going into the Risk Dose Exposure Reports module and clicking Summary Report, and then clicking View Last Report.
4.12.4 Reading, Printing and Saving a Summary Report

Once the summary report is created, the user can view each page by using the forward and back keys on the menu. The menu also includes the icons to print, refresh and export the report. The menu will also allow you to zoom in, or search the report for specific words.

When exporting the report, you have the option of saving the report in any of four different formats, MS Word, Adobe Acrobat, RTF format and Excel. Once you select the format, the file can be saved to your computer for printing at a later time or for attachment to other documents. Exporting the program to Excel will allow the user to perform additional analyses on the model results.

4.12.5 Using the Information in the New Summary Report

The Summary Report for Dietary Exposures has four sections.

User Inputs

The first section is two pages long and provides a record of all inputs for the model run that produced the data and allows other users to exactly duplicate a model run. The inputs include the name of the Input files (.rkg files that define the toxicity of the pesticide, the .res files that contain the dietary residue data and the *.twc files that define the seasonal and regional residues of pesticides in tapwater) and the data and time of their creation. Note the length of the name of the input files is limited to 25 characters. Files with longer names are truncated at 25 characters.

The inputs also document all of the user-defined options for the model run. These provide a simple one page summary of the model run.

You can assign a name to the model run and provide a description of the assumption, purpose or other relevant documentation of the run. The title and the description are
printed out on the first page. The second page provides a printout of the toxicity data used in the analysis. This page includes the data on the acute and chronic toxicity data and the cancer potency data that are used in the analysis. This data includes both the NOAEL/LOAEL/Benchmark Dose and the number and size of the uncertainty and FQPA factors. The determination of the acute and chronic percent Relative Potency Factor (%RfD) will be based on the aPAD and cPAD if a value is specified for the acute and chronic FQPA factor. If no value is provided, the acute and chronic % RfD will be based on the acute and chronic RfD.

Graphs

The second section provides simple graphical outputs of the findings most often used in decision making. There are three bar charts representing the 95th, 99th and 99.9th percentiles of the random day for each of the age categories. The data used to create this chart is taken from Table 4-1, Structure of Residue, Use and Processing Input File, of this Manual.

If no toxicity data is available on the pesticides, then only the acute exposures will be graphed.
4.12.6 Findings for Specific Age categories

The third section provides detailed information on the acute exposures for each of the age categories. This section contains from 1 to 9 pages of tables. Each page presents a table for one of the age categories selected in the user profiles. These tables provide detailed information on the exposures and risks for each age group. These data can be used as a first level of drill-down for the exposures. (Note: To obtain stable estimates at the 99.9\textsuperscript{th} percentile at least 5,000, and preferably 10,000, individuals should be simulated.)

The tables present two types of data. The first type is information on how exposures from diet and tapwater vary across seasons and for different genders. Since both the foods consumed and the tapwater and dietary residues can vary with the season, the exposures and risks will vary as well. LifeLine\textsuperscript{TM} Version 4.4 allows you to specify different residues for each of the four seasons. Second the tables provide estimates of the average exposures for a season and the highest exposure that happens on any day of the season. These measures are provided to give additional perspective to the random day exposure that has been the only measure available before LifeLine\textsuperscript{TM} Version 4.4 software became available.

If no toxicity data is available on the pesticides, then only the acute exposures will be presented and the values for the MOE and \% RfD portions of the table will be blank.

Summary Tables

The final section of the report has a series of five Summary Tables that present information on the acute, chronic and cancer risks. There are two tables on acute risks (Tables 1 and 3). Table 1 presents the same data as the figures in Section 2. This table displays the distribution of exposures and related risk attributable to the differences between one individual and other. This approach is technically the more appropriate method for estimating percentiles of exposure and risk for the U.S. population. However, it may require that the model simulate exposures for at least 10,000 individuals to provide a stable 99.9\textsuperscript{th} percentile. This may require a long period of time for model runs.

Table 3 presents acute risks where data from multiple days from one individual are treated as if they came from multiple individuals. The approach can provide a stable estimate with smaller numbers of simulated individuals. For many pesticides, only 2,500 individuals are needed to provide stable estimates of the 99.9\textsuperscript{th} percentile. The SAS program developed by HED uses this approach to analyze the LifeLine\textsuperscript{TM} Version 4.4 data.

Tables 2 and 4 present information on chronic risks. LifeLine\textsuperscript{TM} Version 4.4 (and V4.3) unlike earlier software, provides distributions of the chronic exposure and risks and not just the exposure and risk to the average individual. These tables present the values for the mean and the 95\textsuperscript{th}, 99\textsuperscript{th} and 99.9\textsuperscript{th} percentiles. Table 2 presents the distribution of exposures and related risk that reflects only the differences between one individual and
other. This approach is technically the appropriate method for estimating percentiles of exposure and risk for the U.S. population. However, as with the acute exposures in Table 1, the model may require the simulation of 10,000 individuals in order to produce stable estimates of the 99.9th percentile.

Table 4 presents the chronic risk where data from multiple years in the exposure history of an individual are treated as if they came from multiple individuals. When applied to dietary exposures, this approach will often give similar answers to the approach used in Table 2. The approach can provide a stable estimate with smaller numbers of simulated individuals. For many pesticides, only 2,500 individuals are needed to provide stable estimates of the 99.9th percentile. The SAS program developed by HED uses this approach to analyze the LifeLine™ Version 4.4 data.

Table 5 presents a distribution of lifetime average daily exposures and corresponding cancer risks. LifeLine™ Version 4.4, unlike earlier software, provides distributions of the lifetime risks and not just the mean lifetime average daily exposure and risk. These tables present the values for the mean and the 95th, 99th and 99.9th percentiles.

If no toxicity data is available on the pesticides, then only the acute, chronic and lifetime exposures will be presented and the values for the MOE, % RfD and cancer risk portions of the table will be omitted.

### 4.12.7 Using the Summary Report

The purpose of the Dietary Exposure Summary Report is to support the use of the LifeLine™ Version 4.4 software in regulatory decision making. The report is designed to provide, in one place, all the information that has historically been used in the pesticide registration process. In addition, the report provides additional information to fill in the background for the bare numbers. This additional information is to help provide perspective to decision makers and registrants on the meaning of the exposure and risk estimates. In addition to this background the report provides an easy method of performing an initial drill-down on the sources of high levels of exposure. For example, the report provides the ability to determine if exposures and risk vary across seasons or if there are gender-based differences in dose. Finally, the report can be exported and attached to printed or electronic documents to provide a complete record of the analysis and results.

When using the Summary Report it is helpful to keep the following in mind.

1. Where food (and not tapwater) is a substantial contributor to exposure and where Tables 1 and 2 are known to give similar results, then run LifeLine™ Version 4.4 with 2,500 individuals and use the results in Table 3, 4 and 5 to evaluate the pesticide.
2. If you wish to run larger numbers of children you can lower the age range from 85 to age 20 and run up to 40,000 individuals.
3. If you wish to evaluate females aged 13-49 then you can limit the population to females.
4. Larger runs will lengthen the time taken to create the summary report