3.0 Dietary Exposure

Approach Used

Exposure presented to humans via their diets from the use of organophosphorus pesticides on crops, either domestically or in countries from which food is imported, can be estimated according to well-established techniques used by EPA for setting tolerances on commodities. The use of the pesticide on crops can be estimated from its registered use, marketing information and occurrence in monitoring studies. The size and probability of occurrence of the residues on commodities or commodity parts come from monitoring results, or calculations using related surrogate crops. Between the field and the consumer's plate, there are many stages of processing, washing, storage and distribution that influence the dissipation or concentration of the residue in the crops as they become ingredients in the ready-to-eat foods. These data and the calculations and assumptions applied to them to derive the residue files for the OP chemicals included in the cumulative risk assessment have been described by EPA in the June 11, 2002 Revised OP Cumulative Risk Assessment and earlier documents found on the EPA web site http://www.epa.gov/pesticide/cumulative/. The LifeLine Group was given the files containing these residue values for use in the LifeLine™ model. They were used in a procedure described below, without modification or elaboration. A brief description of those files is presented here to explain the components of the dietary exposure and risk assessment.

The EPA compiled the residue values for the individual OP chemicals from monitoring data and related information. These residue values were then converted to Methamidophos equivalent residues using a Relative Potency Factor (RPF) approach. This process yielded one listing of index chemical residues (the Methamidophos equivalent residues) on all of the commodities, and those values contained adjustments for the relative potency of the component pesticides, the effects of processing, and other adjustment factors as needed.

EPA then converted this list of residues for the index chemical into a file format that could be

imported into the DEEM-FCID™ software licensed by EPA. Those files were created by EPA using ACCESS™ database software. These files are publicly available on the EPA web site. (These will be discussed in more detail in this chapter.) These files, in the same format as applied to the DEEM-FCID™ software, were imported directly into LifeLine™ Version 2.0 software that could automatically convert the file structure into a file structure appropriate for the LifeLine™ model. This information was then converted by the LifeLine™ model into a visible listing of the foods, as defined in the 1994-96, 98 Continuing Survey of Food Intake by Individuals (CSFII 94-96, 98) that could have a residue because of these crop residues. For each CSFII food, LifeLine™ calculates and displays the distribution of residues that result from the distribution of residues on the commodities that are ingredients in those foods. This complete listing of the index chemical residues on foods provides a basis for calculating dietary exposure. The daily menus for the individuals in the LifeLine™ population detail the amount of each food eaten. Together, these data yield the daily exposure presented to the individuals in the population from the use of the OP pesticides on the crops. Details of this process follow in this chapter.

OP Pesticides and Their Residues

The following pesticides are represented in the dietary risk assessment:

acephate	azinphos methyl	chlorpyrifos
diazinon	dichlorvos	dimethoate
disulfoton	ethoprop	malathion
methidathion	methamidophos	mevinphos
oxydemeton-methyl	methyl-parathion	phorate
phosalone	phosmet	pirimiphos-methyl
terbuphos	tribufos	

Each of these OP pesticides have tolerances assigned for crops considered in the risk assessment,

but not all of the pesticides' crop uses are included in the development of OPCRA.R98. Uses that are being discontinued or, in the opinion of EPA, are unlikely to contribute any residue to the processed food have not been included in the assessment. The decisions to include or not include were made prior to this assessment. Additional information on these residues are contained in the June 11 assessment documentation and in the Reregistration Eligibility Documents for each of the OP chemicals.

The values for the residues of these OP chemicals on agricultural commodities came from the following sources:

1. Residue monitoring data from the US Department of Agriculture's Pesticide Data Program (USDA-PDP)
2. Food and Drug Administration Center for Food Safety and Applied Nutrition (FDA/CFSAN) surveillance monitoring data.
3. Market Basket Study of OP Residues in Apple Sauce sponsored by the Apple Processors Association (for apple sauce and baby food apple sauce).
4. FDA/CFSAN Total Diet Study

Details of these studies are contained in the Appendices of the June 11 EPA Risk Assessment. A complete summary of the analyses of OP pesticides and metabolites on each food commodity in the database is also provided in Appendix III.C.2 of that report.

PDP monitoring data on 44 food commodities monitored between 1994 and 2000 were used. Food processing factors were applied to those foods residue values and specific chemical/commodity pairs to represent likely residues on cooked and processed foods in the analysis. In some cases, PDP residue data were used as surrogate data where monitoring information on those specific commodities were not available. This was done according to guidelines and methodologies described in the OPP/HED SOP 99.3 (USEPA, 1999) guidance document.

The details of how these residues were considered and compiled are contained in the following EPA documents, available on the EPA Website.

1. The Sources of Residue Inputs for the Assessment of the Cumulative Dietary Exposure to Organophosphorus pesticides on Foods.
2. Summary of Residue Monitoring Data on Organophosphorus Pesticides on Foods (PDP/1994-2000 & Apple Growers Market Basked Study on Apple Sauce: 1999
3. A Summary of FDA Total Diet Study Analyses for Organophosphorus Pesticides on Meats (1991-1999)
4. Permissible Crop Translations for Pesticide Monitoring Data
5. Processing Factors Used in Estimating Residues of OP Pesticides in Food Commodities
6. Translation of Residue Source Data to CSFII Food Forms
7. DEEM-FCID Inputs for OP Cumulative Exposure Assessment
8. Use Patterns Considered in OP Cumulative Assessment for Foods
9. Co-Occurrence of Organophosphorus Pesticides on PDP Samples, 1994-1999

Components of the Index Chemical Residue File

Currently available risk analysis tools require that only one chemical residue be considered in an analysis. While most of the individual commodities have multiple residues and processing factors, the residues must be presented as if they were the same chemical. Thus, EPA created an "index chemical" to which all other OP pesticides were "converted" mathematically. The index chemical is Methamidophos. To the residues of Methamidophos are added the "mathematically corrected residues" of each other pesticide found on that crop to yield a total crop-specific residue of the index chemical, representing all of the OP pesticides expected to be on that crop. This crop-specific index chemical residue could be further corrected for factors related to the dissipation of the organophosphorous pesticides on the commodity as it passed through processing en route to the consumer's plate.

The three factors used in the conversion of the chemical specific residues on a commodity to the index chemical residues are:

Relative Toxicity. The potency of each chemical to inhibit brain cholinesterase activity in female rats was compared to that endpoint for Methamidophos, the index chemical. Relative toxicity relates to only this endpoint.

FQPA Factor. The Food Quality Protection Act of 1996 requires an additional safety factor to be applied when data are inadequate to quantify the toxicity to sensitive subpopulations (infants, children, etc.) The analysis presented in this report represents the FQPA factors assigned by EPA to each OP as of June 2002.

Relative Potency Factor (RPF). Relative Toxicity Factor X FQPA Factor. This factor is used to relate the potency of each OP to the index chemical, Methamidophos.

Text in the following paragraphs are taken from the June 11, 2002 Cumulative Risk Assessment to describe the OP Cumulative Risk Assessment Food Residue Database (OPCRA Food Residue Database) created by EPA in a relational database. This database and the functions described here were provided to The LifeLine Group and were used, without amendment for the exposure and risk assessment discussed in this document. However, because all components that make up the index chemical residue file are contained within the relational database and associated queries, an assessor can change the input parameters, generate new residue chemical files and perform a different exposure and risk assessment using LifeLine™ Version 2.0. The EPA relational database and queries were originally constructed by EPA as a tool to merge the residues from many chemicals and associated information about processing effects into a single file that could be used in the DEEM-FCID™ model licensed by EPA. These files can now also be used in the LifeLine™ Version 2.0 software.

The OPCRA Food Residue Database contains more than 1.5 million records of analytical data and sample information. It also contains several thousand additional records of processing

factors. The OPCRA Food Residue Database is organized as a series of tables with these (and other) records. The tables of data are interrelated via a relational database structure that also permits the data to be parameters within functions, constructed in the relational database. The entire OPCRA relational database is provided on the EPA website, as an ACCESS™ file. The four major data tables contained within it are:

1. Residue data tables: about 1.5 million records containing essentially all of the PDP sample and analyses data for OP pesticides as well as other residue data compiled from FDA and the Apple Sauce Market Basket Survey.
2. Processing factor data table; containing all relevant processing factors for specific food form/chemical combinations. Appendix III.C.5. of the June 11 OP Cumulative Risk Assessment is extracted from these data.
3. Relative Potency Factor (RPF) Table containing the RPF for each chemical in the dietary part of the OP cumulative risk assessment.
4. Translation Table, providing bridging links between PDP commodity codes, such as AJ (apple juice), and all corresponding DEEM™ food forms, such as Apple, juice cooked;canned;cook meth N/S (not specified). This table allows the assignments of translation of data between PDP commodities also, such as cantaloup data to watermelon food forms. Appendix III.C.6 of the June 11 OP Cumulative Risk Assessment summarizes the links used in this assessment.

These four tables are linked through common fields, including pesticide codes and commodity codes. Calculation queries are coded into the database so that all the pertinent residue records can be extracted, necessary calculations made to apply the appropriate factors and results sorted and stored in formats for further analysis.

A cumulative residue calculation query performs the necessary calculation, extracting the various parameters needed from the four tables described above. The calculation is performed on all of the food samples that are of interest and the results are compiled in text files containing the cumulative distributions for each commodity of interest. These Residue Data Files (RDF) are the

files that are imported into LifeLine™ Version 2.0 to begin the dietary exposure and risk assessment.

Each text file contains a header with sample information (number of values, number of detects, number of zeros, average of residues) and all of the cumulative residue values for a single food form, sorted in descending order. For those foods that are highly blended before consumption, the distributions are converted to a single average value.

By maintaining all of the calculation parameters in separate tables within the EPA OPCRA Food Residue Database, it is possible to create new index chemical residue files representing different RPFs or other factors, by replacing or adding data to the appropriate table. For example a specific chemical can be omitted from the entire process by assigning it a value of zero in the RPF table. Specific chemical/commodity combinations can be selectively omitted by entering a zero value for that pair in the processing factor table.

The individual chemical/crop contributions to the overall dietary exposure and index crop residue file can be ascertained by working this process in reverse, using the OPCRA Food Residue Database. All necessary information is contained within the relational database, but it is a tedious process, and not within the scope of this assessment.

Translating from Crop Residues to Food Residues

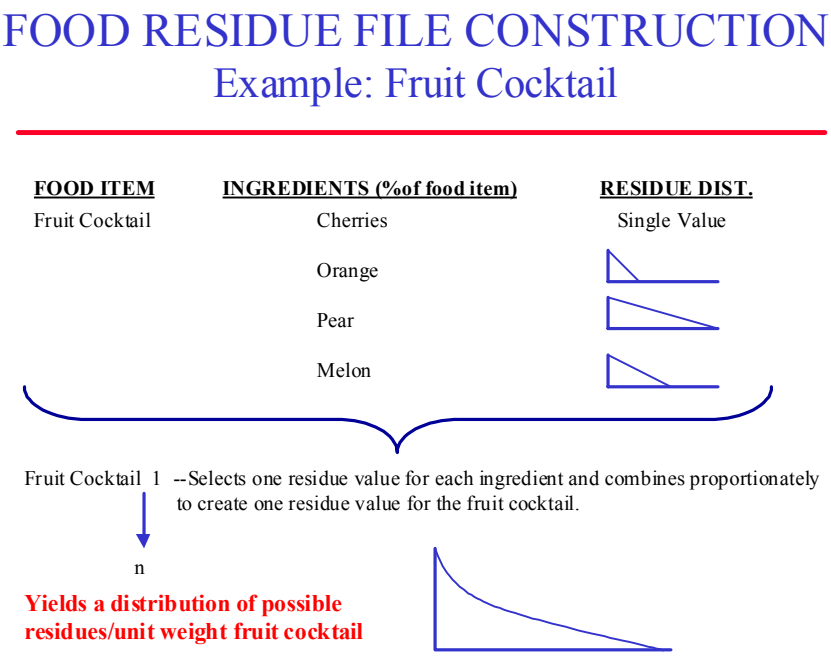
The Residue Data Files (RDF) created in the EPA OPCRA Food Residue Database can be imported into the LifeLine™ Version 2.0 *Food Residue Translator* module. These RDF files must be accompanied by the OPCRA.R98 file provided by EPA, available with the data files publicly available from EPA on the Website. This file is an organizational file specific to the OPCRA assessment as EPA has constructed it. The file catalogues the RDF files that the analysis system is expecting to see, the placement of those files in the architecture of the analysis system and other related information. This file should be contained in the same file address as all the

RDF files so they can be loaded into the LifeLine™ model in an orderly fashion.

The LifeLine ™ *Food Residue Translator* is the module into which the information about commodity residues, processing factors and other residue modifying factors are entered. It translates this information into a listing of the foods (as eaten) that could contain residues as a result of the residues on the agricultural commodities. This translation from crop residues to food residues uses files of food recipes, called translation files, created by the US Department of Agriculture and the US Environmental Protection Agency. This translation file contains the basic ingredients for each of the foods reported as eaten in the CSFII food survey. The residues on each ingredient are from the residue distributions on each crop. A simplified illustration of this process is presented in Figure 3.1.

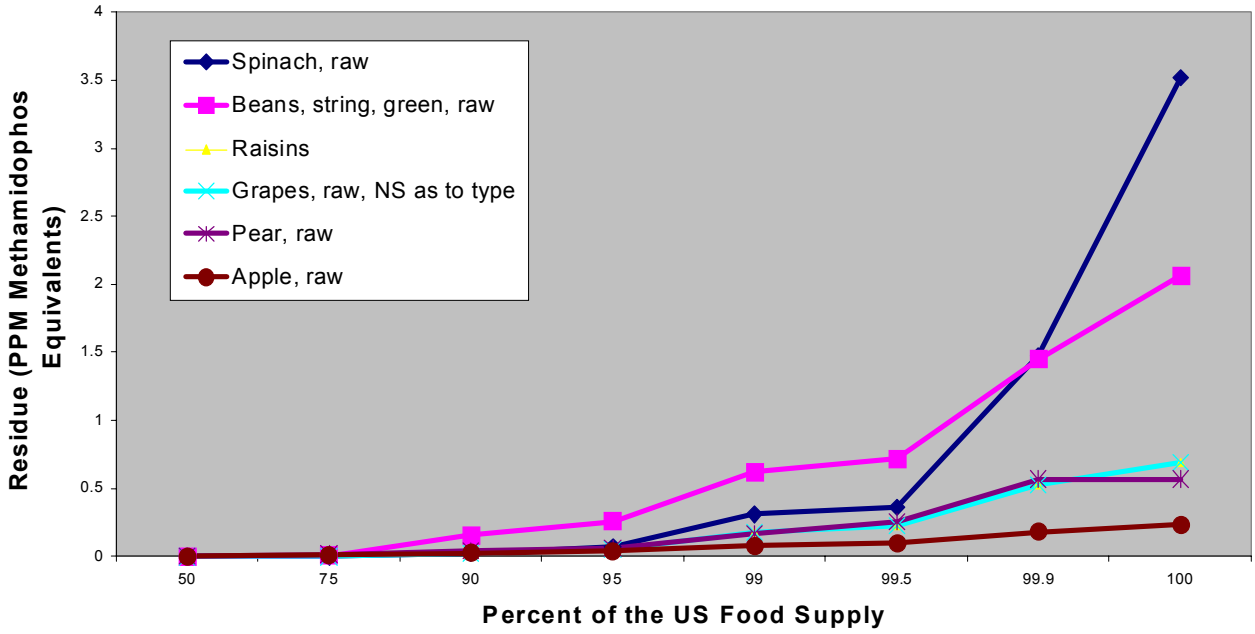
The *Food Residue Translator* can accept data on individual crops, entire groups of crops (Crop Groups as defined by EPA), or on food forms of the crops. It also accommodates data related to the percent of the crop (or food form or crop group) that may be treated by a given pesticide. Another section permits the assessor to enter information about the effects of processing procedures employed to prepare food from the raw agricultural crops.

Figure 3.1



In this assessment, none of these data entry fields are used directly by the assessor. Instead, the RDF files and associated OPCRA.R98 files are imported directly into the LifeLine™ model. The RDF files contain all of this information, as described above. The operation of the LifeLine™ software is described in detail in the Technical Manual and Users Manual that accompany the software. A brief description of the process for importing existing files into LifeLine Version 2.0 is provided in Appendix B of this Report.The *Food Residue Translator* presents a distribution of residues predicted to occur on each food, given the input data about crop residue, processing effects and other modifiers built into the OP residue data files. This listing can be viewed in its entirety, or can be sorted to present the foods with the highest residues (at the maximum point on their distribution). Figure 3.2 is a graphical representation of six of these highest-residue foods.

Figure 3.2 Distribution of Food Residues



The exposure and risk distributions can be viewed in the *Risk-Dose-Exposure Generator*. For all analyses performed on the seasonal basis, LifeLine™ records the CSFII record used to calculate the dietary exposure. Thus, for any person in any season of any year, the dietary record can be retrieved showing all of the foods consumed and the amount of food consumed. The distribution of residues predicted to exist on those foods can be found in the output of the *Food Residue Translator*, as shown above. The user can thus derive the drivers for any point on the exposure and risk distributions for analyses done with the seasonal draw.

Food Consumption Data

This series of surveys conducted by USDA used a stratified area probability sample of individuals residing in households in the U.S. Households represented a cross section of the population of the 48 conterminous states and the District of Columbia, although low-income households were intentionally over-sampled. Interviewing took place over the entire year for

each year of the survey. The surveys obtained reports of dietary intake (food and beverages consumed both at home and away from home) of all individuals in survey households for the survey days.

Households and individuals were surveyed in all four seasons and on all days of the week. In addition to information on food consumption, the survey collected physiological and demographic data such as sex, age, self-reported height and weight, ethnic group, pregnancy and lactation status, and household income. This information permits sorting and aggregation of data, as well as tags for bridging to other data sets within LifeLine™. The survey samples included nursing infants, but consumption of breast milk was not estimated in the survey.

Food intake was recorded by time of day and by eating occasion (breakfast, brunch, lunch, dinner, supper and snacks) as defined by the respondent. Separate entries were made in the database for each food consumed. Quantities of foods and beverages consumed were recorded in household measures, weights, dimensions or common units (e.g. slice), and then were converted to grams by USDA.

Two fundamental changes in the 1994-1996, 1998 CSFII as compared to the earlier 1989-91 survey are most noteworthy. First, rather than collecting data on three sequential days from each individual, the survey explicitly collected data on two *non-sequential* days for each individual. Thus, whatever temporal dependencies exist in the earlier survey (as opposed to patterns of consumption that are characteristic of a sampled individual over a prolonged period), different day-to-day patterns should be seen in the more recent survey. In LifeLine™, each day of survey within the 2-day survey sample are treated as independent survey records, not linked to the same individual. The Technical Manual explains this technique and the reasons for it.

Second, because the basic survey design was found to collect less data than desired on the diets of children, in 1998 a focused survey of *children's* diets was conducted. This was designed in such a way as to permit combination of these data with those collected in the general survey between 1994 and 1996, and results in a far richer sample of children's diets than was available

in earlier surveys. For example, the 1989-1991 survey included records from 204 different individuals between the ages of 1 and 4. The 1994-1996, 1998 survey, in contrast, contained records for 5,886 children in this age range. The CSFII data were examined to find dietary profiles that may be unique, and to justify groupings of respondent records based on explicitly-identified similarities. The effort to identify patterns of dietary behavior considered both the characteristics of the reporting individuals and the characteristics or reported behavior. The parameters contained in the dietary profile that were examined for this purpose were body mass index, caloric intake, eating frequencies, foods eaten per eating occasion, number of foods eaten per occasion, food selection overall, and mass of food eaten.

These parameters were examined together within a matrix of age, sex, and season. There were too few infants less than one year of age to allow analysis of trends in eating by month of age although it was apparent that significant differences do exist between early infancy and 9-12 month-olds.

An effort was made to find natural patterns in these dietary descriptors, such as a decrease in the number of meals, or the increase in the number of different foods consumed in a day, from infancy to adulthood. Overall, there were surprisingly few differences observed between males and females of the same age (there are differences in total consumption that reflect differences in body weight). When taken together, these observations allowed the food records to be separated into age-based bins. The data supported the following bins based on age (seasons were binned separately within each age category):

Bin 1: Nursing infants less than one year
Bin 2: Non-nursing infants less than one year
Bin 3: Age 1 year
Bin 4: Age 2 years
Bin 5: Age 3 years
Bin 6: Age 4 years
Bin 7: Age 5 years

Bin 8: Ages 6-7 years
Bin 9: Ages 8-11 years
Bin 10:Ages 12-14 years
Bin 11:Ages 15-25
Bin 12:Ages 26 and above

Exposure Calculation Options

There are two options for combining the food residue values with the food consumption values to yield daily exposure calculations within the *LifeLine* module that calculates the exposure and risk. Given that the CSFII data are not longitudinal surveys where the same individuals are monitored over long periods of time, the dietary intake data do not necessarily reflect the menu choices that could be made by a person given that one day's menu selection may be influenced by the selection from the previous day.

Residue values for all of the crops are also not from longitudinal sampling plans. The distributions of food residues represent the range of residues that be in or on a food, and from that distribution the model selects a new residue each day.

Thus, we must use "snapshot' residue and food consumption data to simulate a longitudinal exposure scenario. LifeLine ™ provides these two analysis options. First, the model can draw a new food consumption record every day within the season and draw a new residue value from the distribution of residue values for each food on the dietary record. Second the model can draw a single day's dietary record for a person and hold that dietary record (food consumption) steady over the entire season. For each day in the season, however, a new residue value is matched to each food on the dietary record. The value of having these two options is discussed in Chapter 7.

The figures 3.3 and 3.4 present a graphical description of these options.

Figure 3.3.

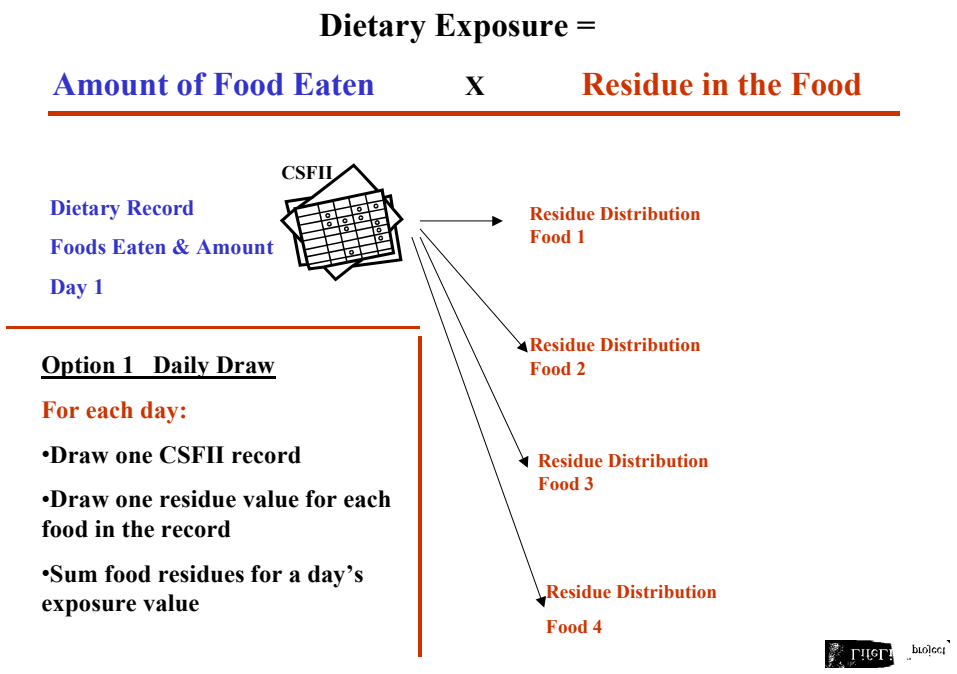
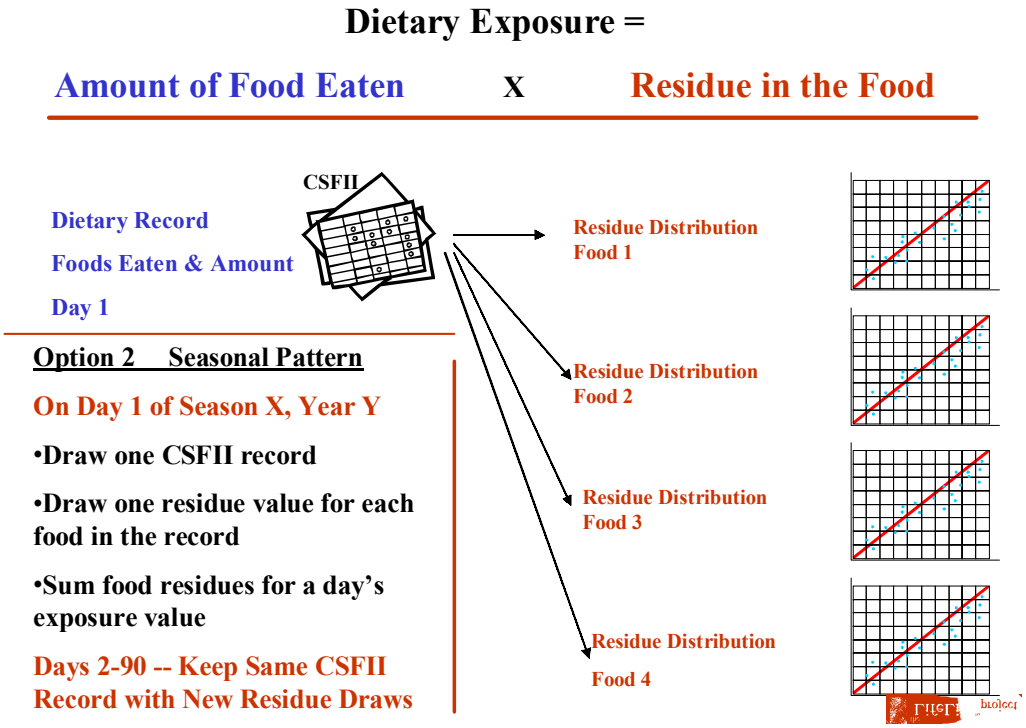


Figure 3.4



Use of Modifying Factors

The LifeLine™ Software was designed to permit the user to enter Uncertainty Factors and Modification Factors (such as the FQPA Factor) to user-selected age and/or gender analyses. For the assessment of the OP pesticides, however, this capability is not applied because the FQPA factor has already been applied in the EPA calculation of reference residues. (See Chapter 2). The consequence of this methodology is that the FQPA factor applies to all ages of both genders, and in already incorporated into the "exposure" profiles created with the options described above.

The assessor could elect to apply different FQPA factors to the assessment by electing that option within the LifeLine™ assessment, specifying the gender and ages to which it should apply. However, this will increase the FQPA factor for all chemicals in the reference doses calculated by EPA and used in this assessment, rather than being applied to selected chemicals within the list of pesticides. Changes to individual pesticide FQPA factors can be accommodated only by changing the EPA files.

For the dietary residues, one can assess the EPA food residue file, created in ACCESS, and available on the EPA website with the EPA OPCRA Http://www.epa.gov/pesticides/cumulative Changes to the factors can be made therein, generating new food residue files with the relative residues (relative to the index chemical, Methamidophos). Those files can than be imported to the *Food Residue Translator*.