6.0 Risk Characterization

LifeLine™ Version 2.0 provides a number of options for characterizing cumulative exposures and risks. The following is a description of the outputs used in the OP cumulative risk assessment.

Assessing Cumulative Risk Total Margin of Exposure

In this assessment LLG has used same approach for the evaluation cumulative risk for organophosphate pesticides as the June 11 Assessment. Under this approach cumulative risk is evaluated using a total margin of exposure:

$$TotalMOE = \frac{1}{\frac{1}{MOE_{Oral}} + \frac{1}{MOE_{Dermal}} + \frac{1}{MOE_{Inhalation}}}$$

MOE_{Oral} is defined as the ratio of the oral point of departure for Methamidophos to the sum of the products of the oral doses for the various OP pesticides that co-occur on a single day and the Oral RPF for the pesticides.

$$MOE_{Oral} = \frac{OralPoint of Departure}{\sum_i OralDose_i \bullet OralRPF_i}$$

The values of MOE_{Dermal} and $MOE_{Inhalation}$ are defined in a parallel fashion.

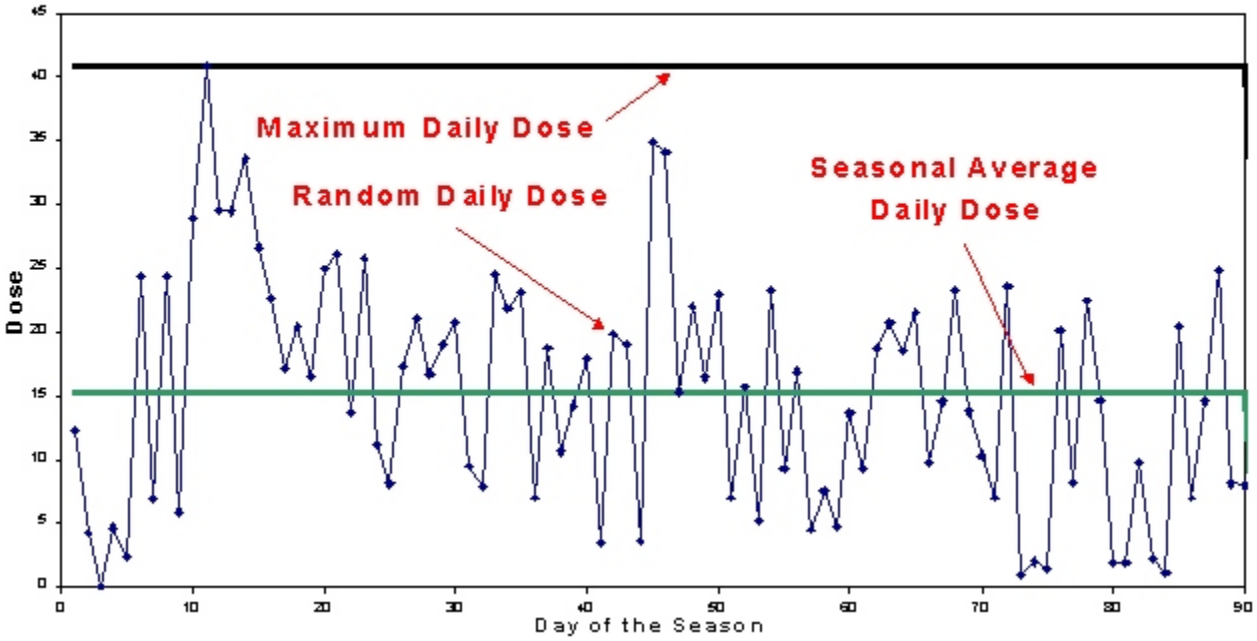
Where the risks are evaluated for doses occurring over period of time longer than one day, the same equation is used but the average dose of the OP pesticides over the period of time.

Risk Characterization and LifeLine Exposure Metrics

In the June 11 assessment EPA described the cumulative risks using 365 separate cumulative distributions, one for each day of a hypothetical calendar year. LifeLine™ does not use this format. Instead LifeLine™ characterizes the risks in a population over a calendar year by using three measures of exposure. For the one day exposures, the three measures are:

1. Average of the daily doses that occur in a season (average day).
2. The daily doses that occur on a randomly selected day during the season (random day).
3. The highest dose that occurs on any given day of a season (maximum day).

Figure 5.1 LifeLine Version 2.0 Exposure Metrics



These measures are discussed in detail in the Technical Manual for LifeLine. Figure 5-1 presents the three metrics graphically. The figure presents the daily doses for one individual over an entire season (90 or 91 days). LifeLine™ Version 2.0 determines the daily doses for each day however only average, maximum, and random day doses are saved for output.

LifeLine™ Version 2.0 also allows the user to investigate the average of the doses that occur over multiple consecutive days. Any duration of "n" days from n = 2 to n = 365 can be investigated. For each season a total of 90 (or 91) n-day averages are created. For example if a 7-day average is required then days 1-7, 2-8, 3-9,... are averaged to produce the 7-day averages[1].

For periods of time greater than one day, the exposure metrics are defined as:

1. Average of the n-day average doses that occur on the periods ending on one of the days of the season (average n-day average).

[1] The 7-day averages for the first six days of the month are taken from the prior season.

2. The n-day average dose for the period that ends on a randomly selected day during the season (random n-day average).
3. The highest n-day average doses that occur on any period ending on a day of a season (maximum n-day average).

In the case of MOEs, the outputs are similar. LifeLine™ Version 2.0 produces three measures of the MOEs. For the one day exposures, the three metrics are:

1. The total and route specific MOEs that are based on the average of the daily doses that occur in a season (average day MOE).
2. The total and route specific MOEs that are based on the daily doses that occur on a randomly selected day during the season (random day MOE).
3. The total and route specific MOEs that are based on the highest dose that occurs on any given day of a season (maximum day MOE).

Because the term "maximum day" in maximum day MOE refers to the dose used to derive the MOE, this measure of the individual's risks actually has the lowest value for any day of the season.

The determination of the maximum day MOE is determined independently for each route and for the total MOE. Thus, the maximum MOE for inhalation may come from one day during a season and the maximum MOE from dermal from another day. However, the total MOE is always based on the route specific doses that occur to an individual on the same day.

The values of the MOEs for periods longer than a single day are based on the average doses for the selected periods. Thus the 7-day average maximum day total MOE is the lowest total MOE that occurs in a season as the result of the averages of the route-specific doses taken from a seven consecutive day period during that season.

Finally, LifeLine™ Version 2.0 uses the data on each of the four seasons to derive the equivalent measures for an entire year. The determination of the annual values is calculated in the following manner.

1. The average annual MOE is the MOE based on the average of the four seasonal average doses.
2. The annual random day is randomly selected from the four seasonal random day MOEs.
3. The maximum annual MOE is the lowest of the four seasonal maximum MOEs.

Uncertainty in Longitudinal Estimates of Exposure

The lack of longitudinal data for both the dietary record and daily activity patterns introduces uncertainty to the estimates of doses over longer periods of time and in the prediction of the maximum day dose. A perspective on the size of this uncertainty can be obtained by taking two different approaches for modeling longitudinal exposures. One approach is to hold a dietary intake record steady for an individual for an entire season (Seasonal Draw) but drawing new residue values daily from the full distribution of residues that could be on the foods in that record. This assumes that a person could eat the same diet for every day of the season, but the foods could contain different levels of the pesticide. In addition under this approach, two activity patterns are selected (one for week days and one for weekend days). These records are repeated for each week day and weekend day of the season. Thus, the child performs the same weekly cycle of activities throughout the season with only the residues on residential media varying.

The second approach is to choose a different dietary record on every day (Daily Draw). Under this option a new dietary record and activity pattern is drawn every day. This assumes that the person chooses a unique diet every day, uninfluenced by the menu from the day before (no leftovers) and a new activity pattern. Additional information on the two options can be found in the LifeLine Technical Manual.

Neither of these approaches represents a fully plausible model of an individual's longitudinal behavior. However, the first approach will tend to underestimate the daily variation of an individual since the daily diet and activities will be held constant for long periods of time. The second approach will tend to overestimate variation since it will include both inter day variation and inter individual variation. If the difference between the results produced by the two scenarios is small, it suggests that the uncertainty due to the lack of longitudinal data is likely to be small.

LifeLine Outputs and Risk Characterizations

None of the outputs of LifeLine Version 2.0 exactly matches the simulations used in the June 11 assessment. The June 11 assessment used software that was based on a different approach for simulating the distribution of doses across a population. However, the metric that most closely approximates the dietary portion of the June 11 assessment is the random day output.

The random day output can be best understood as a snapshot of the distribution of the doses and MOEs that occur on a single day in a selected season/age or year/age. The maximum day output can be viewed as the Lowest MOE that occurs on any day of the specified season/age or year/age. This random day output has a draw back in that it does not always identify the highest dose that could occur in the population for rare exposure events. The maximum day measurement

provides such a measure. This output can be understood as the MOE associated with the highest dose that occurs on any day of a season (or year). This measure captures the rare exposure events better than the random day.