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MCP Rewrite Workgroup

Ch. 21E Risk Assessments
How Conservative Are They?

As many of you are all too aware, a continuing comment made by the regulated community is that the Ch. 21E risk assessment process seriously overestimates risk because of the compounding of "conservative" assumptions throughout the dose-response and exposure assessment portions of those risk assessments. To date, we have not had a good handle on just how conservative the overall risk estimates are. Members of the Superfund Advisory Committee have expressed an interest in hearing about the exposure assumptions used in the Short Form, no doubt to serve as a starting point for a discussion of what some members expect are "overly conservative" risk estimates generated by the Short Form. It would be in the best interest of BWSC and DEP as a whole to get a handle on just how conservative the 21E risk estimates are.

It would benefit everyone involved to understand the nature of conservatism up front rather than have discussions and arguments about the "appropriate" values for exposure parameters in a "too conservative!", "is not!" Lite beer commercial mode. We need to identify the degree of conservatism in these assessments and risk managers should decide if it reflects the appropriate risk management position. Previous controversies about exposure assumptions have actually been controversies about the overall "conservatism" of the entire risk assessment process and the resulting clean-up requirements. Although this issue is surfacing with respect to Short Form assumptions, these discussions are relevant to all 21E risk assessments and not just to those conducted with the Short Form (and to risk assessments in other programs as well).

I would like to point out one very important consideration. The Streamlined Risk Assessment project was designed to make the current 21E risk assessment process less costly, less time-consuming and less frustrating. The Streamlined Risk Assessment project was NOT DESIGNED TO CHANGE THE RISK ASSESSMENT APPROACH and it was NOT DESIGNED TO RELAX THE LEVEL OF HEALTH PROTECTION provided by the Statute or MCP. If, during the development and review of the Short Form, we gain more understanding of risk assessment and risk management, and that understanding is incorporated into a better approach, that will be an added benefit to the program and the agency.

The major goal was to provide a quick,inexpensive risk assessment tool which produces risk estimates which are consistent with the current 21E risk assessment approach and process and which could be reviewed and approved with minimal DEP resources. The current version of the Short Form is very similar to the Risk Assessment approach contained in the DEQE 1989 Guidance for Risk Characterization. The external review draft of the Short Form and its accompanying documentation does offer (for comment) some alternative exposure

assessment approaches and assumptions intended to make the the assessments more realistic and less uncertain.

The current Short Form does contain a number of assumptions which intentionally do NOT represent worst case situations. Many of the assumptions are not as "conservative" as those required by the Region I Superfund Program. This is an attempt to characterize the "average exposure" for the maximally exposed individual.

It is indeed important to identify the nature of conservatism which is built into the current MCP risk assessment process and into the current Residential Short Form in order to fully evaluate the risk management criteria which are applied to the risk estimates generated for disposal sites. Until recently, there has not been a simple way to characterize the nature of the conservatism in an easily understood manner. However, there are now software packages which can be used to evaluate the uncertainty in risk estimates and to put risk estimates from our assessments into perspective.

Our risk assessments focus on theoretical individuals (receptors) who have certain exposure patterns. This "strawman" or "strawwoman" is assigned various exposure characteristics. For example, the female receptor is assumed to weigh 62 kg, consumes 2 liters of drinking water per day, drinks water at home 365 days per year, and lives at that "site" for 75 years. These assumptions are made for the theoretical receptor because it is difficult or impossible to measure these exposure parameters for each receptor who is or might be exposed at the site, and we would not want to conduct a risk assessment for each individual person due to time and expense involved. The assumptions for the theoretical receptor have historically been made in a way which is "conservative", i.e. the values for each characteristic are unlikely to underestimate exposure for the majority of potential receptors.

It is obvious that not every adult receptor weighs 62 kg or consumes exactly 2 liters of drinking water per day. Some adults weigh more, some less. Some adults drink more or less than 2 liters per day. In a given population these bodyweights and intake rates vary, i.e. there is a distribution of bodyweights and a distribution of intake rates for that population. Each distribution will have values which cluster around some central value such as a mean or median value(50th percentile value) with fewer values which vary considerably from the central values.

Focused Risk Assessments - It is important to know what portion of an exposed population would have exposure charcteristics similar to those assumed for the "strawman", what portion of the population might have overall exposures and risks higher than those estimated for the "strawman", and how high the exposures and risks might be for those individuals with exposures higher than those of the "strawman". Risk assessments may be conducted in such a way as to estimate worst case risks,average risks,and best case risks in order to bracket the range of risks to assist risk managers in decision-making.

Sensitivity Analysis - Another method for putting risk assessments in perspective is to conduct sensitivity analysis to determine how variation in one parameter at a time affects the overall risk estimate. For example, we might calculate risks several different times using different values for bodyweight or water intake rate. In doing this, we might find that possible variation in water intake among individuals would have a greater impact on risk estimates than would variation in bodyweight for example.

Monte Carlo and Monte Carlo Sensitivity Analysis - There is a way to more thoroughly evaluate the uncertainty in a risk assessment. A software program called @RISK is capable of simulating risk estimates for large numbers of theoretical individuals within a theoretical population using the actual distributions of values for the parameters rather than the single esimates which are traditionally used. Using this software package, it is possible to construct a distribution of likely risks for a theoretical population using actual probability distributions of exposure and toxicty values. We can use this technique to put the 21E risk assessments in some quantitative perspective. This technique, however, cannot at this time completely characterize the uncertainty or degree of conservatism in a complex multi-media risk assessment. We do not have documented distributions for the cancer potency factors and reference doses, nor do we have distributions for many of the soil-related ingestion and dermal contact rates.

Uncertainty Analysis Exercise - In order to get a general idea of the nature of the conservatism in a typical Ch. 21E risk assessment, we can do an uncertainty analysis for a very simple example: for an adult receptor, we can evaluate cancer risks associated with ingestion (only) exposures to benzene in drinking water. We can estimate the risk for a female adult using the standard set of assumptions used by the 21E program (and by Division of Water Supply). Then , we can generate a profile of risks to a theoretical population exposed to the same concentration of benzene assuming that each individual in the population will have bodyweight, tap water intake rate, and residence time in a single dwelling assigned to them in a random manner using the known distributions of these parameters in the US population and we can assign a cancer potency factor for each individual risk estimate using the estimated distribution of values for that factor. We can use this profile to put the standard risk estimates in some perspective.

Standard Risk Calculation - The theoretical scenario involves a female adult exposed to 5 ug/liter benzene in drinking water. We are concerned in this example only with ingestion of the drinking water (no dermal or inhalation exposures are evaluated). Table 1 shows the factors and standard values used to calculate cancer risk for this scenario as well as the distributions for Ingestion Rate,

Residence Time, Bodyweight and Benzene Potency Factor which are used in the Monte Carlo analysis. The equation for calculating Excess Lifetime cancer risk is also shown at the bottom of the Table.

Table I. - Summary of Standard Exposure and Toxicity Factors and Distributions used in Monte Carlo Analysis

Factor	Units	Standard Value	Distribution type	Mean	Std Dev
Conc	ug/l	5			
Ingestion Rate	l/day	2	Lognormal	1.1	0.434
RAF		1			
F	ev/day	1			
D1	day/ev	1			
D2	yrs	75	Lognormal	8	12
BW	kg	62	Normal	65.4	13
AP	yrs	75			
Potency	1/(mg/kg/d)	0.029	Lognormal	0.0131	0.012
Conversion Factor	ug/mg	1000			
ELCR = Conc x Ingest Rate x RAF x D1 x D2 x Potency/(BW x AP x Conv Factor)					
	"Standard" ELCR = 5E-06				

In the above Table,

1. Conc = Concentration of benzene in drinking water = 5 ug/liter
2. Ingestion Rate = Drinking water ingestion rate of 2 liter/day
3. RAF = Relative Absorption Factor of 1
4. F = Frequency of exposure, 365 days/year
5. D1 = Duration of each exposure event = 1 day
6. D2 = Duration of exposure at the "site" = 75 years
7. BW = Bodyweight = 62 kg
8. AP = Averaging period = lifetime = 75 years
9. Potency = Cancer potency factor for benzene = 0.029 /(mg/kg/day)

Standard Risk Estimate - Using those standard factors, the Excess Lifetime Cancer Risk (ELCR) is estimated to be 5E-06 or 5 in one million for the assumed 75 year exposure.

Monte Carlo Analysis of Risk - We can then assign distributions of values to ingestion rate, D2 (duration at one residence), bodyweight, and potency factor. We can then use the @RISK software package to estimate risks for a population of 10,000 people exposed to 5 ug/liter benzene. Each individual in the population would be assigned ingestion rate, residence time, bodyweight and potency randomly from the distributions which are available for those factors. The results of that exercise are summarized in Figures 1 and 2 and in Table 2.

In Figure 1, you see the expected distribution of risks in the theoretical population of 10,000 people. This is a "probability density" graph. In simple terms, it is a histogram showing the frequency at which given risks appear in the population. The x-axis plots cancer risk. On that axis, "4" represents 4E-06 (4 in one million) risk. Recall, our risk estimate using standard
assumptions is 5E-06. The Y-axis plots the probability for each risk interval in the histogram. Quickly, you can see that a very small portion of the population (much less than 1%) has risks that high. The average risk estimate for the population is 0.12E-06 or 0.12 in one million. This average risk estimate is approximately 40 times lower than the estimate using standard assumptions. Figure 2 shows the same information in a slightly different manner.

Figure 2 shows a Cumulative Probabilty graph. Using this graph we determine what percentage of the population has risks higher or lower than a given risk estimate. For a given risk estimate located on the x-axis, we move up to intersect the graph, then move over horizontally to read a cumulative probability value for that risk estimate of interest. That numerical probability is the probability (or in this case the percentage of the population) which has risk estimates higher than the the risk estimate of concern. On this graph, the vertical dashed line identifies the average risk estimate identified in the paragraph above (0.12 in one million).

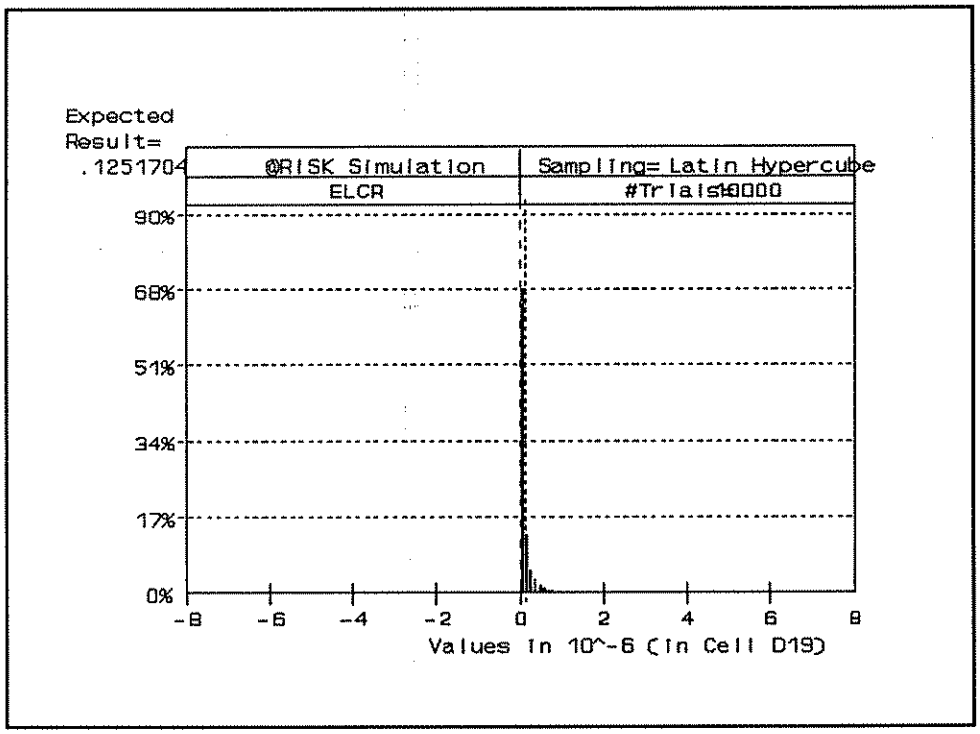


Figure 1 - Cancer Risk Probability Density Graph - Random values drawn from distributions for water intake rate, residence time, bodyweight, and potency factors.

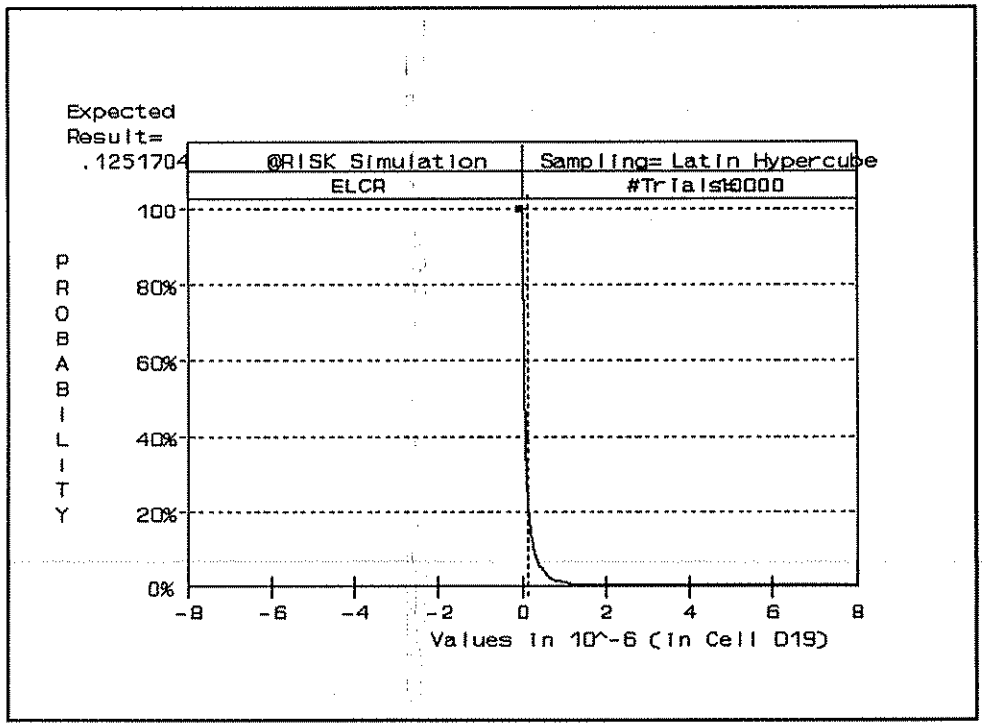


Figure 2 - Cancer Risk Cumulative Probability Graph. Random values drawn from distributions of water intake rate, residence time, bodyweight, and potency factor.

For example, the mean cancer risk estimate from the @Risk simulation, 0.12E-06, intersects the graph at a probability of about 23%. That means that 23% of the population (or 2300 people in 10,000) would be expected to have risk greater than 0.12 in one million. Also, the cancer risk estimate resulting from our standard assumptions, 5E-06, intersects the graph at a probability of 0.06%. That means that 0.06% of the population (or 6 people in 10,000) would be expected to have risk greater than 5 in one million. This graph also tells us that 1.5% (or 150 people in 10,000) would be expected to have risk greater than 1E-06 (1 in one million) and that 25% (or 2500 people in 10,000) would be expected to have risk greater than 1E-07 (1 in ten million). Presented another way, 75% of the population would be expected to have risks lower than 1E-07 (1 in ten million).

NOTE: Although Figure 1 tells us that the mean or average risk estimate is 0.12E-06, Figure 2 tells us that roughly 77% of the population has risk estimates lower than that average estimate.

Table 2 - Summary of Cumulative Probability Distribution for Cancer Risk. Ingestion Rate, Bodyweight, Residence Time, and Potency Factor Assigned Distributions. All other parameters held constant.

Cancer Risk	Portion of Population with Risk Greater than First Column	Portion of Population with Risk Less than First Column
10.3 in one million	virtually zero	virtually 100%
5 in one million	0.06%	99.94%
1 in one million	1.55%	98.45%
0.5 in one million	4.44%	95.56%
0.1 in one million	25%	75%
0.045 in one million	50%	50%
0.0002 in one million	virtually 100%	virtually zero

These summary statistics put the cancer risk estimate derived via our standard exposure and toxicity assumptions into some perspective. It is clear that the estimate is conservative, that it is not quite worst case, and that more than 99.9% of the adult population would be expected to have lower risks. It would be interesting to investigate which factors have the greatest "conservative" influence in this exercise.

Monte Carlo Sensitivity Analysis - It is possible to evaluate how big an impact each of the current standard assumptions has on the risk estimate by simulating risks for a theoretical population while randomly assigning values from a distribution for 1 factor(bodyweight, for example) while holding the values for all other factors constant. I

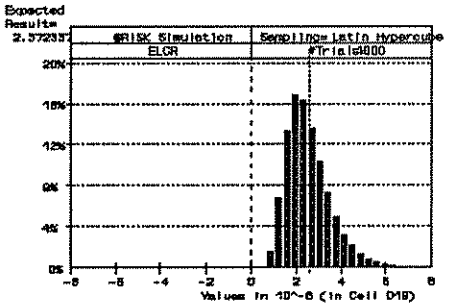
have done this separately for tap water intake rate, residence time, bodyweight and potency factor. The probability density graphs for those four exercises are shown in Figure 3. The factor or parameter whose standard value has the greatest impact on risk estimates is the one which "moves" the bulk of the histogram farthest from the 5E-06 risk estimate generated by our standard calculation. The average risk, indicated by the vertiacl dashed line and presented as the "expected result" (times 10^-6) in the upper left hand corner of each graph, can be compared directly to the risk estimate generated via our standard assumptions (5E-06).

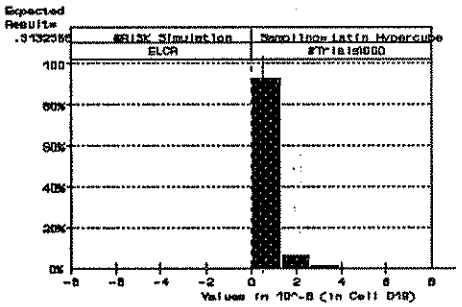
It is clear from Figure 3 that Residence Time values used in our standard calculation impact the risk estimates much more than do Drinking Water Intake Rate, Bodyweight, and Potency Factor for this benzene drinking water scenario. The Residence Time values drawn from the distribution yield an "average" risk estimate of 0.51 in one million, roughly 10 times lower than the estimate from our standard scenario. Of the other factors considered here, varying the water intake rate yielded an average risk roughly half of the standard estimate as did the variation in the benzene potency factor. The variation in the bodyweight yielded an "average" risk which is roughly 10% lower than the standard estimate. This is not surprising, since our standard assessment uses a 50th percentile value for bodyweight.

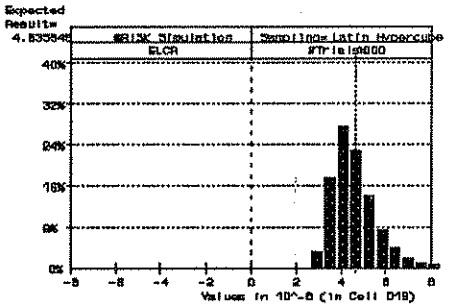
CONCLUSIONS

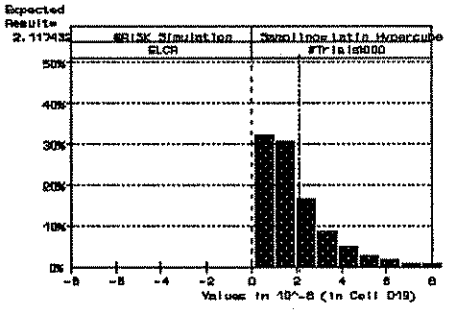
From this INTRODUCTORY exercise, we can see that compounded conservative assumptions can indeed result in very conservative risk estimates. This very simplistic exercise also is able to identify where some of the "conservatism" comes from. The Residence Time of 75 years does make this analysis very conservative. This beginning work should serve as a catalyst for more work to characterize the uncertainty in Ch. 21E risk assessment and hopefully for further discussions of the "exposure assumptions" typically used and how they relate to the risk management criteria in the MCP. UNTIL FURTHER DETAILED WORK IS CONDUCTED ON MULTIPLE CHEMICAL, MULTIPLE PATHWAY ASSESSMENTS, WE SHOULD NOT MAKE ANY RASH DECISIONS BASED ON THIS SINGLE EXERCISE.

Figure 3 - Cancer Risk Probability Density Graphs. One parameter varied per graph. From top to bottom: Water Intake Rate
Residence Time (D2)
Bodyweight
Potency Factor









FOOD FOR THOUGHT

If the standard residence time(duration of exposure) were 30 years (90th percentile of that distribution) or 8 years (50th percentile of that distribution), the standard risk estimate would be 2.5 in one million and 0.5 in one million repectively. Those risk estimates would fall at roughly the 99.8 percentile and 95.5 percentiles of the risk distribution shown in Figure 2. These percentiles seem substantially more defendable than the 99.94 percentile value which is generated by the "standard" assumptions presented earlier in this discussion.

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