SUMMARY REPORT

on the application of

Monte Carlo Simulation Methodology

for the

Palmerton Zinc Superfund Site

Operable Unit #3

Human Health Risk Assessment

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for:

The Palmerton Citizens For A Clean Environment

In Response to Task Schedule #12

OVERVIEW

The following report has been prepared in response to Task Schedule #12, item 2), which requests information regarding the use of Monte Carlo methodology as part of the human health risk assessment presently being prepared for Operable Unit #3 of the Palmerton Zinc Superfund Site in Palmerton, Pennsylvania.

A review of correspondence from EPA Remedial Project Manager Mr. Frederick N. Mac Millan to Palmerton Environmental Task Force (PETF) Steering Committee and Risk Assessment Subcommittee Member Ms. Delores K. Ziegenfus, dated June 12, 1995, documents that the EPA has considered and concurred with a request by the PETF Risk Assessment Subcommittee to utilize Monte Carlo methodology in calculations associated with the ongoing risk assessment for the Borough of Palmerton. This correspondence raised several potentially important questions, and these were expressed to the PCCE in a written memorandum dated July 26, 1995 (attached). A contingent of PCCE members attended the Palmerton Environmental Task Force meeting of July 26, 1995, and addressed EPA officials with several of the prepared questions.

In response, and as partial satisfaction to the PCCE's inquiries, EPA Remedial Project Manager Mr. Frederick N. Mac Millan attached a copy of the February 1994 EPA Region III Risk Assessment Technical Guidance Manual titled: "*Use of Monte Carlo Simulation in Risk Assessments*", to an August 9, 1995 correspondence addressed to PCCE President Louise Calvin. The PCCE reviewed the content of the guidance manual, and requested clarification of several issues from the Technical Assistants project team from McTish, Kunkel and Associates (MKA). MKA Project Manager Robert H. Hosking Jr., and Environmental Toxicologist Dr. Dale Bruns, Ph.D., reviewed several pertinent documents in preparation for this report. These include:

1. **EPA**, 1994. *Use of Monte Carlo Simulation in Risk Assessments* (U.S. Environmental Protection Agency Hazardous Waste Management Division, Office of Superfund Programs, EPA Region III, Philadelphia, PA 19107. EPA903-F-94-001, February 1994)

2. **Dakins, M.E., J.E. Toll and M.J. Small**. 1994. Risk-Based Environmental Remediation: Decision Framework and Role of Uncertainty. *Environ. Toxicol. and Chem.* 13(12):1907-1915.

3. **Renner, R**. 1995. When is Lead a Health Risk? *Environ. Sci. & Tech.* 29(6)256A-261A.

In addition, MKA Project Manager Robert H. Hosking Jr. also reviewed the following articles for additional background information pertinent to risk assessments at metals contaminated sites:

4. **Calabrese, E.J., R. Barnes, E.J. Stanek III, H. Pastides, C.E. Gilbert, P. Veneman, X. Wang, A. Lasztity, and P.T. Kostecki**. 1989. How Much Soil Do Young Children Ingest: An Epidemiologic Study. *Regulatory Toxicology and Pharmacology* **10**, 123-137.

5. **Stanek, E.J., and E.J. Calabrese**. 1995. Daily Estimates of Soil Ingestion in Children. *Environ. Health Perspect.* 103:276-285

6. **Sullivan, B**. August 1995. Part 503 Sludge Rules: Applicability to Metals Contaminated Soils. *The National Environmental Journal.* 40-44

In general, the questions prepared by MKA Project Manager Robert Hosking Jr., for the Palmerton Environmental Task Force meeting of July 26, 1995, were developed to gain further insight into why the PETF Risk Assessment Subcommittee had requested the use of Monte Carlo methodology for calculations associated with the Borough of Palmerton risk assessment. Although the EPA Region III Risk Assessment Technical Guidance Manual on the "*Use of Monte Carlo Simulation in Risk Assessments*" provides important information about EPA policies regarding the use of Monte Carlo methodology, it did not answer all of the questions prepared for the July 26 PETF meeting. Consequently the essential question, (why was the use of Monte Carlo methodology requested by the PETF Risk Assessment Subcommittee?) remains unanswered.

In an attempt to gain further insight into the use of Monte Carlo methodology, a series of articles on risk assessment and uncertainty analysis were reviewed (see the lists of references provided on pages 1 and 2). These articles have been numbered 1-6 to make cross referencing less cumbersome.

DISCUSSION

Article #1, the EPA Technical Guidance Manual on the Use of Monte Carlo Simulation in Risk Assessments provides an informative overview of what Monte Carlo simulations are, what their advantages are, what their limitations are, and how they are to be applied during the risk assessment process.

In simple terms, a Monte Carlo Simulation is a statistical technique involving multiple, randomly selected "what-if" scenarios for each calculation (EPA, 1994). Dakins, et.al. (1994) provides a more detailed definition, and describes Monte Carlo methods as... "techniques for generating a representative sample from probability density functions (pdfs) of the model inputs and parameters and propagating that sample through the mathematical model to produce a corresponding sample from the pdf of the model prediction. The procedure involves a random selection of values, one from each input pdf, which together define a scenario that is used in the model to compute an output value. The procedure is repeated for *N* iterations yielding *N* output values, which characterize the uncertainty in the model prediction." This definition demonstrates how Monte Carlo techniques are used to evaluate uncertainty and variability in risk estimates. The ratio of different output values to the number of iterations, and the range of those output values provides information about uncertainty. Dakins, et.al. (1994) distinguishes between two different types of uncertainty. The first type, called *ignorance* is due to variables that have a definite but unknown value; while the second type, called *variability* is due to variables with an "underlying probabilistic structure arising from stochastic variability (Dakins, et.al., 1994). These terms will be addressed later in the discussion of EPA's guidance on the use and limitations to the use of Monte Carlo techniques.

Current "standard" EPA risk assessment methods express health risks as single numerical values, or single point estimates. As Dr. Bruns described during one of his earlier PCCE presentations on risk assessment, when uncertainty is encountered during the risk assessment process, it is typically compensated for by assigning an uncertainty factor which normally results in the assignment of a more conservative risk value. The assignment of a more conservative risk value is intended to assure that the risk assessment can be used to establish exposure levels that are protective of human and/or ecosystem health (Dakins et. al. 1994). For multi-media contaminants and/or multiple contaminant scenarios like Palmerton, this can be a complicated process, since there may be uncertainty about any number of input values, as well as uncertainty about the risk assessment models to which those values are applied. The assignment of multiple conservative risk factors may result in the development of risk values that are several orders of magnitude greater than the range of values that would be observed or measured in an actual exposure scenario (i.e. in an epidemiological study).

According to EPA, the advantage of Monte Carlo Simulation is that it provides Risk Managers with better information about the uncertainty and variability surrounding the risk estimate (EPA, 1994). Instead of generating a single point estimate, as current standard risk assessment methods do, Monte Carlo methods generate multiple descriptors of risk, because it provides a probability distribution. An illustration of a probability distribution is provided by the bell shaped curve, which describes a range of risk values, their frequency, an average value, and other statistical information. The suggestion is that this additional information allows the Risk Manager to make a more informed decision about the appropriate risk management technique, including the most appropriate clean-up standards.

The use of Monte Carlo Simulations for risk assessments is becoming more widely accepted by the scientific and regulatory communities, and as such is being published more frequently in peer-reviewed scientific journals and in the proceedings of scientific conferences. A brief overview of the available literature indicates that the use of Monte Carlo methodology, or other similar forms of uncertainty analyses, have been practiced and accepted by the scientific community since at least the mid 1960's. Although the use of Monte Carlo methods for conducting risk assessments is still in the research stage of implementation, some regulators have already approved it's use for developing clean-up standards. For example, Pennsylvania Act 2 of 1995, the *Land Recycling and Environmental Remediation Standards Act*, identifies Monte Carlo simulations as an appropriate statistical technique for establishing valid site-specific cleanup standards. It is noteworthy that the exact language used in the act: "*Use of appropriate statistical techniques, including, but not limited to, Monte Carlo simulations, to establish statistically valid cleanup standards.*", does not require the use of other statistical techniques, such as those that generate single numerical values. This is at not consistent with the EPA Region III Technical Guidance Manual on Risk Assessment titled: *Use of Monte Carlo Simulation in Risk Assessments.*

I asked Mr. Kenneth Symms, Ph.D., one of the many individuals who contributed to the development of Act 2, and a proponent of Monte Carlo simulations, why the Legislature did not follow the lead of U.S. EPA Region III Toxicologist Dr. Roy L. Smith (also a proponent of Monte Carlo simulations), and..." require single point risk estimates, prepared under current national guidance, in conjunction with optional Monte Carlo simulations". Mr. Symms responded that the Legislature generally lacks the level of scientific sophistication required to understand such matters, and most Legislators were probably unaware of the limitations to using Monte Carlo methods for conducting risk assessments when they cast their votes.

The EPA Technical Guidance Manual on the Use of Monte Carlo Simulation in Risk Assessments clearly defines the limitations of the methodology. The first limitation is that currently available Monte Carlo software cannot distinguish between uncertainty and variability. EPA, using human characteristics to illustrate their point define **variability** as "well described differences between individuals". For example, the assimilation rate from exposure to a particular contaminant may **vary** from individual to individual (due to body weight, nutritional status, etc), but given the same level of exposure, all individuals will assimilate the contaminant within a given range. **Uncertainty**, on the other hand is a factor that cannot be reasonably predicted within a certain range. This is essentially the same type of uncertainty that Dakins et. al. (1994) termed *ignorance*. EPA defines **uncertainty** as a factor that is due to circumstances which are unknown. The example given about the frequency and duration of trespass suggests that there is simply not enough information available to predict human behavior or assign a specific range of exposure resulting from different behavior patterns. Some people may make it their business to trespass where they are not permitted, while others may strictly adhere to the law and never cross onto a property where access is restricted due to contamination. In a more extreme exposure scenario, the "trespasser" may routinely visit the bag houses to play with the dust. In this example of uncertainty, exposure levels may range from the maximum exposure concentration possible (i.e. the "trespasser" who plays with the bag house dust), to almost no exposure at all (i.e. the individual who never enters the contaminated property).

To use an example pertinent to Palmerton, consider the predicted blood lead level that would result from ingesting a specific quantity of soil contaminated with a specific concentration of lead every day for a specific number of years. Using a model such as the Integrated Exposure Uptake Biokinetic Model (IEUBK), it would be possible to assign a predicted range of blood lead values expected from this exposure scenario. The **variability** in this example would be due to age, nutritional status, and possibly other physiological factors. This is **variability**. Now consider the range of behavior between individuals that would affect one factor, such as the quantity of contaminated soil ingested. Two factors that might affect the quantity of soil ingested, in this oversimplification, may be the amount of time spent outside, and the frequency with which they wash their hands. There is no way to accurately predict this range of behavior, and furthermore there is no way to correlate how often an individual goes outside with how often they wash their hands. Some individuals may go outside often and wash their hands regularly, while other individuals may go outside infrequently, but hardly ever wash their hands (or vice versa since there are four discrete possibilities in this simplified example). This is **uncertainty**. The statistical difference between **variability** and **uncertainty** is that **variability** can usually be expressed as a finite range of values, with a sufficient level of confidence. **Uncertainty**, on the other hand may represent an infinite range of values with no apparent pattern of distribution (this may or may not be the case, since uncertainty could occur in data sets that have a finite range, but no apparent pattern of distribution). The limitation inherent in the current software's inability to differentiate between **variability** and **uncertainty** reduces the value of the procedure as a form of sensitivity analysis, and also introduces the possibility of generating erroneous or irrelevant results.

The second limitation identified by the EPA Guidance Manual is also of serious concern to the PCCE. The EPA manual states that ignoring correlations among exposure variables can bias Monte Carlo calculations. The caveat that possible correlations are seldom available makes this limitation even more significant. Consider the scenario describing the uncertainty of human behavior, provided in the previous paragraph. There may very well be important correlations between how frequently people go outside, and how often they wash their hands. Similarly, there probably are important correlations between the number of houses with old peeling lead-based paint, soil lead levels, nutritional status, and distance from the East Plant facility. Depending on the study design and the type of analysis, these correlations may or may not be found to be statistically significant, and would therefore be justifiably disregarded.

The third limitation may also be important. EPA states that "Exposure factors developed from short term studies with large populations may not accurately represent long-term conditions in small populations". A common problem with the scientific method is that the answer generated is a direct result of the question asked. Accounting for bias that results from experimental design is an ongoing challenge to research scientists. Even statistical techniques employed to validate the significance of experimental results, and identify bias in design are subject to contextual misinterpretation. Paramount among contextual variables are the scales of time and space. One would intuitively expect that a risk assessment of residents of the entire Palmerton Valley, measured within a period of a few years, will produce much different values than a risk assessment of the small population that resides within a few blocks of the East Plant, measured over a period of decades.

According to Article #3 ***"When is Lead a Health Risk"***, "...the short half-life of lead in blood (about 35 days) means that for situations in which lead exposure is variable or intermittent, such as cases of environmental exposure, blood lead provides only limited information" (page 259A). The author states further on Page 261A "EPA's new guidance requires site managers and risk assessors to thoroughly delineate the lead contamination at hazardous sites so that they can conduct their analysis on the scale of households and neighborhoods. This emphasis on small-scale risk assessment is certainly a necessary step toward a more realistic, science-based appraisal of risk." The size of the sampling area, the time between sampling dates, and all other spatial and temporal aspects of the study design, as well as the statistical parameters, all need to be scrutinized carefully when this data becomes available.

The fourth limitation of Monte Carlo methodology, identified by EPA, also relates specifically to experimental design and the values of the input data. EPA states that "... the tails of Monte Carlo risk distributions, which are of greatest regulatory interest, are very sensitive to the shape of the input distributions." When conducting risk assessments, Risk Managers are interested in establishing levels of risk that are protective of a specific segment of the population. In most instances (or nearly all cases), it is not considered feasible or even possible to conduct a clean-up that will guarantee every member of the community is free from exposure, or safe from adverse health effects. Instead, Risk Managers will aim for the 95th or the 99th percentile. This is the area referred to as the tails of the Monte Carlo risk distributions.

As an example, consider a common risk assessment scenario. The hazard index is calculated by dividing the average daily dose by the EPA reference dose. Since the EPA reference dose is more or less a constant (usually derived through empirical research with an appropriate level of conservatism), the variable is the average daily dose. The average daily dose is a function of Total Intake, which is calculated with the following formula:

$$\text{Total Intake} = \frac{C \times IR \times EF \times ED}{BW \times AT}$$

Where:
C = Concentration
IR = Intake Rate
EF = Exposure Frequency
ED = Exposure Duration
BW = Body Weight
AT = Averaging Time

Each of these factors is a variable, represented by a range of values. The standard risk assessment technique is to apply the upper bound limit to assure that the risk estimate is protective of the most sensitive segment of the population (usually represented as the 95th percentile or the 99th percentile). What occurs during a Monte Carlo calculation, is that the computer looks at each factor as a distribution (i.e. a bell shaped curve), and randomly selects a point along the curve as the variable for that calculation. By repeating this procedure 10,000 times, the computer generates a risk value that is itself a distribution, as opposed to a single point estimate. In brief, the fourth limitation means that small changes in the distributions of the input data can generate large differences in the tails of the Monte Carlo risk distributions.

CONCLUSION

In general, EPA Region III's guidance on the use of Monte Carlo Simulation in Risk Assessments appears to adequately document the limitations, and provide the necessary guidance, to assure that a reasonable risk assessment is conducted in Palmerton. First and foremost, it is important to remember that the EPA Region III Technical Guidance Manual on the Use of Monte Carlo Simulation in Risk Assessments clearly states: **"The region will continue to require single-point risk estimates, prepared under current national guidance, in conjunction with optional Monte Carlo simulations."** Consequently, as long as current EPA guidance on the Use of Monte Carlo Simulation in Risk Assessments is followed, there will be ample opportunity to compare and contrast the results of the two statistical techniques. As stated previously, this could provide important information related to the accuracy of the data and the ability of the model to accurately predict the human health risks from various exposure scenarios. This may provide valuable information about many of the outstanding questions remaining in Palmerton, such as the relative contribution of various media to elevated blood lead levels, and the relative importance of historic versus current emissions.

The most critical factor that will impact the outcome of the risk assessment at Palmerton will not be the statistical methodology, but the sampling plan, and the representativeness of the input data. Numerous extent of contamination studies have been conducted in Palmerton, and for various reasons, none of them seem to adequately characterize or quantify all of the exposure pathways. Because the impact of exposure to heavy metal contamination is cumulative, the potential contribution of current emissions (including but not limited to ground traction cinders, kiln vapors, and windblown dust and smoke from the cinder pile) should be provided the same level of attention as the contribution of lead based paint. In fact, the multi-media (air, soil, water and paint) and multi-contaminant (lead, arsenic, cadmium and zinc) nature of environmental pollution in Palmerton should be ample justification for applying every valid statistical technique available to the risk assessment process, and then developing an appropriately conservative risk management and remediation program to assure protection of human health.

A few final random comments are in order to address the multiplicity of issues related to risk assessment at Palmerton.

* The article by Rebecca Renner plainly states that..."EPA believes it now has an accurate and scientifically rigorous approach" ... to predicting a community's risk from lead contamination (R. Renner, 1995). The approach discussed in her article places strong emphasis on the Integrated Exposure Uptake Biokinetic model (IEUBK). In general this model has been demonstrated to be fairly accurate at correlating exposure to lead contamination with blood lead levels. The two primary areas of uncertainty identified by Ms. Renner are bioavailability and the ingestion rate.

* Studies conducted by E. J. Calabrese et. al., (1989) and E.J. Stanek and E.J. Calabrese (1995) at the University of Massachusetts School of Public Health illustrate how difficult it is to accurately quantify the soil ingestion rates of children. According to R.Renner (1995), the results of the 1989 study were used by a panel of scientists to argue that EPA overestimated the human health risk of exposure to lead contaminated soil at Smuggler Mountain (Aspen Colorado). However, the most recent research (Stanek and Calabrese 1995) concludes that excessive ingestion may be more common than previously thought. This underscores the need for maintaining an appropriate level of conservatism when conducting risk assessments.

* Finally it should be noted that in some instances, the application of Monte Carlo simulations may result in risk managers selecting a more aggressive remedial action than would result from relying solely on standard deterministic analyses. This was the case in New Bedford Massachusetts, where a clean-up level was developed to maintain an acceptable level of PCB's in flounder tissues. This raises an interesting question. Technical guidance from EPA Region III only allows Monte Carlo techniques to be applied to the assessment of human health risks. If and when an environmental (ecosystem) risk assessment is ever conducted at Palmerton, what cleanup levels will be required to restore ecosystem health. Because we are all living creatures that are an integral part, and ultimately dependent upon, the ecosystem that sustains us, shouldn't an evaluation of human health risks also include a comprehensive evaluation of ecosystem health?

  An honest answer to this question is long overdue.