Quantifying uncertainty in human health risk assessment using probabilistic techniques
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Abstract

Quantitative chemical risk assessment is an increasingly important tool in making risk management decisions in the United States. In such an assessment, available data and information regarding chemical toxicity is combined with estimates of exposure to calculate the likelihood and severity of human health effects. In some circumstances, limitations in evaluating chemical toxicity and exposure potential introduce significant uncertainties into a risk assessment. This paper discusses the use of probabilistic approaches, such as Monte Carlo techniques, to quantify the uncertainty in the human health risk assessment process. Case studies include the evaluation of emissions from an existing commercial hazardous waste incinerator, and the development of remediation levels at a hazardous waste site. These studies indicate that risk estimates which are based on standard regulatory default assumptions regarding toxicity and exposure can be an order of magnitude or more higher than central tendency risk estimates, and may also be significantly higher than 90th or 95th percentile risk estimates which are calculated using probabilistic techniques.

1 Introduction

Traditionally, risk assessment results are expressed as point estimates of risk. Such risk assessments typically incorporate conservative point-estimate exposure parameters, resulting in risk estimates that have a high degree of uncertainty. More recently, however, USEPA has placed increased emphasis on presentation of "a full and complete picture of risk" (USEPA 1992a). Specifically, the Agency has stated that:

"Regarding exposure and risk characterization, it is Agency policy to present information on the range of exposures derived from exposure scenarios and on the use of multiple..."
risk descriptors (i.e., central tendency, high end of individual risk, population risk, important subgroups, if known). . ."

Probabilistic techniques, such as Monte Carlo simulations, can help distinguish so-called “high end” or “reasonable maximum” risks from “typical” or “central tendency” risks.

According to U.S. EPA guidance, reasonable maximum exposure (RME) risks should fall within the 90th to 98th percentile for a population (USEPA 1992b). However, USEPA guidance allows for considerable professional judgment in deciding which combination of individual exposure variables would provide an overall RME estimate. When only upper-bound values are used, the resulting risks are often very conservative, easily exceeding what might reflect a 98th percentile exposure level. To avoid such “worst-case” risk estimates, USEPA guidance states that if “sufficient information about the variability in lifestyles and other factors are available to simulate the distribution through the use of modeling, e.g., Monte Carlo simulation, the estimate from the simulated distribution may be used” (USEPA 1992b).

2 Overview of the Monte Carlo Technique

Monte Carlo analysis is a technique that has been applied to numerous areas affected by random behavior, and over the past decade has been increasingly used in the context of risk assessment. Unlike “point-estimate” risk assessments, Monte Carlo analysis incorporates probability density functions or cumulative frequencies for each variable, instead of using single values to represent exposure variables in the risk formulas. Single values from within these distributions are selected based on their probability (frequency) of occurrence and are combined at random with values from other distributions (for other exposure variables), selected on the same basis, to calculate risk. After these calculations are repeated 5,000 to 10,000 times, the risk results can be presented as distributions that reflect the overall uncertainty in the input values. To provide for greater consistency in the use of probabilistic techniques in regulatory risk assessments, USEPA (1997) recently issued its “Guiding Principles for Monte Carlo Analysis.”

The differences between traditional “point estimate” and Monte Carlo risk evaluations are illustrated in Figures 1 and 2. In Figure 1, the magnitude of exposure (i.e., internal dose) is calculated using “point estimate” input values for exposure duration, exposure time, exposure rate and other exposure factors. The estimated dose is then combined with a
Exposure Duration (X) 20 years
Exposure Time (Y) 350 days/year
Exposure Rate (Z) 2 liters/day
Toxicity (T) 2.0 (mg/kg/day)

\[ f(X,Y,Z...) \]

Dose (mg/kg/day) 1 x 10^{-5}
Point Estimate of Risk

Figure 1. Point estimates of risk

Figure 2. Distribution of risk (Monte Carlo)
chemical specific toxicity criterion (also expressed as a single value), resulting in a point estimate of risk. If high-end values are used for each of the exposure parameters, then the risk estimate may correspond to exposures exceeding the 98th percentile, or even beyond the range expected in the general population. This problem can be partially addressed by combining “high-end” values for some exposure inputs, and “central tendency” values for others. However, use of point estimate values does not provide any indication as to where the risk estimate falls in the overall risk distribution.

Figure 2 illustrates how Monte Carlo techniques can help risk managers by providing more information regarding the range and likelihood of risk. As shown in Figure 2, the basic input exposure parameters are expressed as distributions, rather than point estimates, creating a probabilistic distribution of exposure. At the current time, U.S. regulatory agencies generally require that toxicity criteria be expressed as a single value, even when conducting a Monte Carlo risk assessment. Nevertheless, as shown in Figure 2, the result of a Monte Carlo simulation is an estimated distribution of risk.

Exposure distributions for a Monte Carlo simulation can be developed using readily available data for a variety of common exposure input parameters, including soil ingestion rate, exposed skin surface area, inhalation rate, exposure frequency, exposure duration, and body weight. For example, a cumulative distribution can be used for the body weight of an adult resident or worker in the U.S., with a minimum of 44 kg, a maximum of 107 kg, a 50th percentile of 69 kg and a 95th percentile of 97 kg. This distribution is the adult body weight distribution for both sexes presented in AIHC (1994) and is based on data from USEPA (1990).

Distributions can also be derived to represent exposure duration. For example, a cumulative distribution can be used for the exposure duration of workers. Based on summary data from the Bureau of Labor Statistics (USDOL 1992), occupational exposure duration for workers in the U.S. can be characterized as a cumulative distribution, with a minimum of 0 years, a maximum of 49 years, a 59th percentile of 5 years and a 90th percentile of 19 years. In addition, USEPA’s RME value for occupational exposure duration of 25 years (USEPA 1991) can be assumed as the 95th percentile value of this cumulative distribution. The distribution results in a 50th percentile value of approximately 4 years, which is consistent with the median employee tenure of 4.5 years reported in USDOL (1992). Of course, a different worker exposure duration distribution may apply for specific industries or facilities, or for countries other than the U.S.

In some instances, the Monte Carlo technique can be extended to include source terms in a risk assessment. For example, when evaluating exposures to constituents in soil, data on constituent concentrations can be
represented as a distribution, rather than by a single value (such as the mean or maximum). Fate and transport modeling used to estimate exposures in a Monte Carlo risk assessment can also be based on distributions, rather than point-estimate inputs. For example, ground water modeling can incorporate distributions for physical properties of the aquifer (such as porosity or organic content) as well as the physical/chemical properties of the constituents.

Insufficient information may be available to develop distributions for all input factors used in a risk assessment. In these cases, point estimate input values can be incorporated in the Monte Carlo risk analysis. For example, as previously mentioned, single point estimate toxicity values are typically used even in probabilistic risk assessments at this time.

The benefits of utilizing Monte Carlo techniques in risk assessment are illustrated in the case studies below.

3 Case Studies

3.1 Risk Assessment for a Former Oil Refinery

A former oil refinery site in the Midwest is currently undergoing remediation. Refinery operations were conducted at the site for over 50 years, and resulted in petroleum hydrocarbon contamination of on-site and off-site ground water. Regulatory agencies had also expressed concerns regarding a series of impoundments that had been used at the refinery as part of a wastewater treatment system. The state regulatory agency requested that a risk assessment be performed to help determine whether or not remediation of the impoundments is needed and, if so, to establish a basis for setting site-specific cleanup targets.

It was agreed that land use at the site is likely to remain industrial or commercial in the future. Thus, the on-site evaluation focused on risks to current and future workers. The state agency indicated that it was considering setting a cancer risk target of one-in-one hundred thousand ($1 \times 10^{-5}$) for such workers, although a more stringent target of one-in-one million ($1 \times 10^{-6}$) might also be selected.

Point estimate risk calculations determined that the soil ingestion pathway posed the greatest hypothetical risks to future workers. Based on regulatory default input exposure assumptions, the future risk to workers via soil ingestion were estimated to be about 3 in 100,000 ($3 \times 10^{-5}$), or marginally higher than the $1 \times 10^{-5}$ goal being considered by the state agency.
A Monte Carlo simulation was performed for the soil ingestion pathway, to identify high-end (i.e., 90th percentile) and central tendency (i.e., 50th percentile) exposures and risks, for comparison with the results of the point estimate calculations which were conducted using regulatory default input parameters. The Monte Carlo calculations assumed that the impoundment area would be developed for commercial/industrial use, and were based on exposure parameter distributions derived from the scientific literature. The same toxicity criteria used in the point estimate evaluation were applied in the Monte Carlo simulation.

Figure 3 presents the probabilistic risk estimates calculated using Monte Carlo simulation compared to the risk estimate calculated using point estimate techniques. As shown, 90th percentile risks for future soil ingestion were estimated to be approximately $8 \times 10^{-6}$ (about 4-fold lower than the point estimate result) and the 50th percentile risks were estimated to be about $1 \times 10^{-6}$ (about 30-fold lower than the point estimate result).

Based on the 90th percentile risks calculated by the Monte Carlo simulation, remediation of the impoundments would not be required if a $1 \times 10^{-5}$ risk target is established for on-site workers. If a more stringent $1 \times 10^{-6}$ risk target is selected, some remedial action would be needed, but the cleanup goals would be about four-fold less stringent, reducing remediation costs. If remediation is based on the 50th percentile risk estimate from the Monte Carlo simulation, no remedial action would be required based on either the $1 \times 10^{-5}$ or the $1 \times 10^{-6}$ risk targets under consideration.

### 3.2 Commercial Hazardous Waste Incinerator

The USEPA and the state regulatory agency required a comprehensive risk assessment for a commercial hazardous waste incinerator seeking an operating permit in the Midwest. The assessment included an evaluation of both public health and ecological risks posed by routine stack and fugitive emissions from the facility, as well as risks from potential upsets and accidents. The risk assessment, which was conducted by ENVIRON for USEPA, is considered to represent the state-of-the-art for commercial incinerators.

As part of the uncertainty analysis for the incinerator risk assessment, a Monte Carlo simulation was performed for two constituents of incinerator stack emissions which were driving human health risk estimates based on point estimate risk assessment techniques. Specifically, Monte Carlo simulations were conducted for the organic compound, pentachlorodibenzofuran, and the metal, arsenic, which contributed the
Figure 3: Hypothetical Future Risk to On-Site Workers.

Figure 4: Estimated Cancer Risk for Hypothetical Exposure of Subsistence Farmer.
greatest potential risks to human health through ingestion of locally-produced meat and milk. Exposure to pentachlorodibenzofuran was estimated to pose risks approximately three orders of magnitude greater than exposure to arsenic.

In the Monte Carlo simulation, distributions were developed (when adequate data were available) for emission rates, fate and transport model input parameters, and exposure input parameters. The results of the simulations for pentachlorodibenzofuran are shown in Figure 4.

As shown in Figure 4, “high-end” risk estimates (e.g., the 90th percentile) are approximately $2 \times 10^{-3}$. This is about 20-fold higher than the “central tendency” (i.e., 50th percentile) risk estimate of $1 \times 10^{-6}$. On this basis, USEPA concluded that it is unlikely that the total cancer risk for subsistence farmers, even in the area of maximum impact, would exceed one-in-ten thousand ($1 \times 10^{-4}$) for all constituents of stack emissions combined. USEPA ultimately approved an operating permit for the incinerator facility.

4 References


