

and in populations (e.g., potentially susceptible subpopulations such as children or older adults) also requires a better understanding of how ventilation rates and surface area vary with age or health status. The assumptions and default values for ventilation and surface area currently used by EPA in the RfC methodology (USEPA/600/8-90/066F-1994), as well as those used by other agencies and risk assessors, are evaluated. The scientific basis and the variability in the available data was evaluated for both parameters in humans. The data supporting ventilation parameters indicated a robust correlation with both age and activity patterns as well as an interaction between these variables. In contrast to the fairly well-characterized and supported parameter values for ventilation rate, estimates of surface area for various regions within the respiratory tract are based on scant and highly variable data. Much of the variability in surface area data appears to result from differences in how the region in question is defined anatomically, and differences in the measurement or calculation technique utilized. The results of our analysis is intended to support the development of more reliable and defensible values, and perhaps reduce the uncertainty used in estimating human respiratory tract dosimetry and inhalation exposure hazard assessments.

W9.3 Starr, T.B.; TB Starr and Associates; tbstarr@mindspring.com. **COMPARATIVE ANALYSIS OF BIOLOGICALLY-BASED AND MATHEMATICALLY-BASED DOSE-RESPONSE MODELING FOR COMPLETE DATA SETS.**

This presentation includes a detailed analysis of dose-response modeling using three different methods that approach the data set differently, and a comparison of the interpretations, variations in each method's use of biologically-based and mechanistic data, and the advantages and disadvantages of each method. Copper presents an exemplary study model because of its broad public health implications: (1) the biological processes which are considered in this analysis apply to many other chemicals, (2) it is an essential dietary element, (3) it is the only chemical that has two medically recognized diseases (Menkes, Wilson's) associate with it, at opposite ends of the exposure spectrum, (4) inborn errors of copper metabolism (polymorphisms) can result in severe consequences of toxicity or deficiency, (5) a significant proportion of the human population (=1%) is theoretically heterozygous for these errors, putting large numbers of people at potential risk, (6) significant discoveries have been made in recent years on the mechanisms of control and action of copper, and (7) the results of the analysis has significant implications for copper in the environment, drinking water, and the diet. The body of literature on copper is paradoxically extraordinarily rich in information on mechanism while suffering from a paucity of data directly applicable to elucidating a dose-response relationship. However, while data from toxicological studies can be put into the quantitative units of mass per mass per time, information from mechanistic or molecular studies is qualitative in nature, and thus is inappropriate for quantitative estimates of risk, except insofar as this information allows for a better understanding of uncertainty.

M15.1 Stayner, L., Vrijheid, M., Stram, D.; National Institute for Occupational Safety and Health; lstayner@cdc.gov. **ADDRESSING UNCERTAINTY IN EPIDEMIOLOGICALLY BASED RISK ASSESSMENTS.**

The use of epidemiologic data for quantitative risk assessments (QRA) is becoming increasingly common. Part of the reason for this increase is that using human studies avoids the uncertainties associated with extrapolating from animals to humans. However, using epidemiologic data in QRA introduces a whole other set of uncertainties, which are largely related to the observational nature of epidemiologic data. Of particular concern are issues related to inadequate sample size, unresolved confounding or other biases, inadequate length of follow-up, and errors in the ascertainment of exposures. The issue of errors in the estimation of exposures has been of large concern particularly in occupational studies. We are evaluating methods for estimating confidence intervals that reflect both uncertainties related to random error, and potential errors in exposure using Monte Carlo maximum likelihood methods. These methods will be illustrated using an epidemiological study of nuclear power plant workers.

P2.17 Stephen, K., Greenberg, M., Bukowski, J.; Highland Park High School, Rutgers University, ExxonMobil, Inc.; Kftucker0605.aol.com. **A CURRICULUM MODULE ON RISK ANALYSIS FOR HIGH SCHOOL SCIENCE STUDENTS.**

A curriculum will be developed on risk analysis for high school students in an advanced placement course in chemistry. The module will be part of a new course in Science and Society taught at Highland Park High School in New Jersey. The teacher, a chemist, is developing a module that focuses on the environmental disasters. This project is funded by the ExxonMobil Scholarship fund to Rutgers University and the Society for Risk Analysis.

T15.6 Stern, A.H., Smith, A.E.; New Jersey Department of Environmental Protection; astern@dep.state.nj.us. **THE CORD BLOOD-MATERNAL BLOOD METHYLMERCURY RATIO, AND ITS IMPLICATIONS FOR METHYLMERCURY RISK ASSESSMENT.**

In the current U.S. EPA Reference Dose (RfD) for methylmercury, the one-compartment pharmacokinetic model used to convert fetal cord blood Hg concentration to a maternal intake dose. This requires a ratio relating cord blood Hg concentration to maternal blood Hg concentration. No formal analysis of either the central tendency or variability of the ratio has been done. This variability contributes to the overall variability in the dose estimate. A ratio of 1.0 is implicitly used in the model, but an uncertainty factor adjustment (UF) is applied to the central tendency estimate of dose to address variability in that estimate. Thus, incorporation of the cord/maternal ratio and its variability into the estimate of intake dose could result in a significant change in the value of the RfD. We analyzed studies providing data on the cord/maternal blood Hg ratio, and conducted a Monte Carlo-based meta-analysis of 10 studies meeting all inclusion criteria to generate a comprehensive estimate of the central tendency and variability of the ratio. This analysis results in a recommended central tendency estimate of 1.7, a CV of 0.56, and a 95th percentile of 3.4. By analogy to the impact of the similar hair/blood Hg ratio on the overall variability in the dose estimate, incorporation of the cord/maternal ratio may support a 3-fold UF adjustment to the central tendency estimate of dose to account for pharmacokinetic variability. Whether the information generated in this analysis is sufficient to warrant a revision to the RfD will depend on the outcome of a comprehensive re-analysis of the entire one-compartment model. We are currently engaged in such an analysis.

W5.3 Stern, P.; National Research Council; pstern@nas.edu. **ASSESSMENT OF THE IMPACT OF UNDERSTANDING RISK.**

The 1996 National Academy of Sciences report, *Understanding Risk: Informing Decisions in a Democratic Society* was seen by many as advocating a paradigm shift in the practice of risk analysis from a view that put scientific analysis first to one that emphasized the integration of science with other concerns in ways that would make risk analysis more responsive to the informational needs of all those who might be interested in or affected by the decisions that analysis informs. Paradigm shifts, when they happen, take time. This presentation will consider the extent to which the practice and organization of risk assessment in US federal agencies has changed since 1996 in the directions advocated by that report.

P2.2 Stewart, R.N., Purucker, S.T.; University of Tennessee; u74@ornl.gov. **INITIAL SAMPLE DESIGNS FOR RISK ASSESSMENT.**

Accurate quantification of the levels and spatial extent of contamination for exposure assessment requires well-designed initial sampling schemes. This talk will describe the various initial sample designs, their benefits and drawbacks, as well as detail some case studies of their use. These designs range from judgemental (non-statistically-based) to various statistically-based designs. These latter designs include random, systematic, and radial or nested designs. By making use of grid spacing, probability-based decision rules, and/or assumed hot spot sizes as inputs, initial sampling designs can be generated where no prior information exists or at sites where unbiased sampling schemes are required.

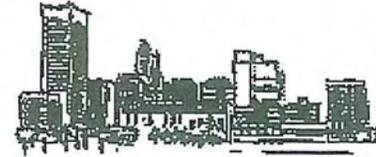
M3.2 Stickers, D.E.; Carnegie Mellon University; des3@andrew.cmu.edu. **THE EVOLUTION OF A REGULATORY LANDSCAPE: THE CASE OF TRANSPORTATION FUELS.**

There continues to be a great deal of interest in reforming the regulatory process. An important area of research that informs this debate concerns questions of how regulations play out after rules are finalized and implementation begins. In this study, I examine this process in detail for the case of risk regulations governing the production, distribution, and use of transportation fuels. Because these rules pertain to an interrelated set of activities, I employ the concept of a regulatory landscape — a term that is rarely defined in any systematic way. The first part of this study develops such a systematic definition for transportation fuels by constructing an original database containing a cross section of regulations promulgated since the late 1960s by the Environmental Protection Agency, the Department of Transportation, and the Department of Labor. Using this database, I describe the evolution of these rules and illustrate how individual actions are linked over time and across agencies. The second part of this study examines questions pertaining to outcomes that occurred after rules were promulgated. To accomplish this, I model the likelihood of various outcomes such as court challenges and the occurrence of unintended consequences based

Society for Risk Analysis



2003 Annual Meeting
Bridging Risk Divides



Baltimore, Maryland
23rd Annual Meeting

December 7-10
Renaissance Harborplace Hotel
Baltimore, Maryland

Final Program