



## Gradient Scientist Develops a Significant Improvement for Human Health Uncertainty Analysis

December 19, 2007, Cambridge, MA. Lorenz R. Rhomberg, Ph.D, a well-known toxicologist and Principal at Gradient Corporation has developed an improved method to characterize uncertainty in human health risk assessment. This approach, termed Hypothesis-based Weight of Evidence is much less ambiguous than existing uncertainty analyses because it uses a more transparent, rational approach to toxicity data from animal studies for which human relevance has not been clearly established, that may contain contradictory test results and/or often require large extrapolations from high to low doses.

According to Dr. Rhomberg, the key to achieving clarity and effective uncertainty analysis is to systematically test the data against proposed hypotheses on why specific study data should predict human risk. He notes, "Although we can neither prove nor disprove numerical risk estimates, we can better lay out the reasoning and evidence (both for and against) to allow rational judgment about which model and data sets best predict risk." Prior uncertainty analysis has simply been a catalogue of possible errors, whereas this new approach allows measurement of how well testing data may serve as evidence."

The new approach developed by Dr. Rhomberg is a systematic way to evaluate each proposed basis for inferring potential human risk. Evidence is arrayed in structured tables to help clarify the consistency or inconsistency of study results for selected hypothesized modes of toxic action (e.g., cancer or kidney disease). Different animal-test responses that might be considered predictive of an effect in humans are evaluated as well. This approach for the first time provides a systematic framework of logic for interpretation of toxicity data as it relates to human risk potential. Rhomberg says, "The aim is to enable productive scientific debate about how to interpret specific study results rather than to argue about whose judgment is right." By segregating the large, qualitative uncertainties about the existence of human hazards from the more statistical issues about dose-response curve fitting and chemical potency calculation, the uncertainty analysis is not only more clear, but, more importantly, can be made quantitative.

Dr. Rhomberg's work has attracted the attention of both industry and government. In addition to his work for companies trying to improve their risk assessment of key chemicals and new technologies, Dr. Rhomberg has been invited to present his method to the US EPA and to a committee of the National Academy of Sciences that is preparing recommendations for improving chemical risk assessment. He also gives public lectures on this topic to explain this new approach.

An expert in quantitative risk assessment, Dr. Rhomberg has been a principal at Gradient Corporation since 1999. Before joining the company, he was on the faculty of the Harvard School of Public Health and, prior to that, a scientist at the US EPA. He has been active in professional groups and environmental policy development through service on panels sponsored by government, industry and such organizations at the National Academy of Sciences and the International Life Sciences Institute. He is author of several books and monographs as well as more than 50 articles on dose-response analysis and probabilistic methods with special experience in chlorinated solvents and endocrine-active agents.

About Gradient Corporation

Gradient Corporation is a nationally recognized environmental and risk science consulting firm with over 20 years of expertise in Toxicology, Risk Assessment, Product Safety, Contaminant Fate and Transport, and Environmental Chemistry. The company employs sound science to devise and implement cost-effective strategies for addressing chemicals in the environment, in the workplace, and in products throughout their life cycles. Gradient's rigorous analysis and competent negotiating skills achieve innovative and value-added solutions to help clients meet their business goals while protecting human health and the environment. From its offices in Cambridge, MA and Seattle, WA, Gradient provides national and international clients with the technical expertise and knowledge required to address their most complex environmental and health related matters. For more information, please visit [www.gradientcorp.com](http://www.gradientcorp.com)

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