RISK ASSESSMENT AND RISK MANAGEMENT

Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. [NRC 1983]

Risk assessment has become a dominant public policy tool for making choices, based on limited resources, to protect public health and the environment. It has been instrumental to the mission of the U. S. Environmental Protection Agency (EPA) as well as other federal agencies in evaluating public health concerns, informing regulatory and technological decisions, prioritizing research needs and funding, and in developing approaches for cost-benefit analysis. [NRC 2009]

The use of commercial chemicals provides benefits such as improving human health and quality of life. Adverse impacts to human health and the environment have also resulted from chemical use. Design and management of the synthesis, production, use and disposal of chemicals can maximize their utility and minimize their potential adverse impacts, ensuring that chemicals can be used safely.

However, the definition of "safe" differs among individuals. In the context of national and international efforts to protect human health and the environment, "safe" is defined by legislators, implemented by regulators and adjudicated by the courts as a level of acceptable risk. These actions are informed by science, but are based on values, politics, economics and other social factors. Science, properly used, informs decision makers about the inherent hazards and the likelihood of adverse health or ecological effects from particular exposures. Scientists can also assess the strength of evidence, and the uncertainties and variability of currently available information. Such risk assessment information should be considered by decision-makers, but cannot on its own be used to determine what is "safe or safer." [NRC 2009]

Risk assessment entails three "…analytic steps—hazard identification, dose-response assessment, and exposure assessment—and a fourth step, risk characterization, in which results of the first three steps are integrated to yield information on the probability that the adverse effects described in hazard identification will occur under the conditions described in exposure assessment. Uncertainty findings from the first three steps are also integrated into risk characterization." [NRC 2009] The process of risk assessment provides information for risk management decisions (See Figure 1).

There is no single set of analytical tests to conduct risk assessment for the wide range of existing and possible chemistries. Rather, risk assessment is a process for selecting appropriate methods to evaluate the impacts associated with life cycle exposures to a chemical at the different stages of commercialization. All of this information is used to inform decisions for chemical risk management.

Additionally, new, more efficient tools are developing for toxicity evaluation, allowing earlier identification of concerns and more accurate appraisals of hazards. Such progress was highlighted in the 2007 NRC report "Toxicity Testing in the 21st Century: A Vision and a

Strategy" and the 2012 NRC report "Exposure Science in the 21st Century: A Vision and A Strategy" [NRC 2012]. As these tools evolve, it will be important to assess best practices and incorporate new strategies as necessary.

References

- National Research Council, 1983. Risk Assessment in the Federal Government: Managing the Process.
- National Research Council, 2007. *Toxicity Testing in the 21st Century: A Vision and a Strategy.*
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Figure 1. A Framework for Risk-Based Decision-Making that Maximizes the Utility of Risk Assessment. **[NRC 2009, p11]**