RISK ASSESSMENT AND RISK MANAGEMENT OF HAZARDOUS MATERIALS

Risk assessment is a formal process for defining the health effects of exposure of individuals, populations, or the environment to chemical substances and hazardous situations. The risk management process weighs policy alternatives and identifies appropriate regulatory actions, 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]

Risk assessment and risk management are also tools that companies also use to mitigate risk. They are practices that can be utilized outside of policy and regulatory work. Responsible companies build engineering controls, policies and procedures to mitigate risks identified as part of a risk assessment before regulatory action is taken. Actions taken on risk assessments can and should go significantly beyond regulatory action (ACC Responsible Care Product Safety Code).

The use of commercial chemicals provides benefits such as improving human and environmental 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 be used on its own 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 have been developed 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,” the 2012 NRC report “Exposure Science in the 21st Century: A Vision and A Strategy” [NRC 2012], the 2017 NRC Report “Using 21st Century Science to Improve Risk-Related Evaluations” (NRC 2017), and the 2018 Workshop Summary “Understanding Pathways to a Paradigm Shift in Toxicity Testing and Decision-Making: Proceedings of a Workshop in Brief” (NRC 2018).

As these tools evolve, it will be important to assess best practices and incorporate new strategies as necessary. A recent description is presented by the United State Environmental Protection Agency [EPA 2023].

References

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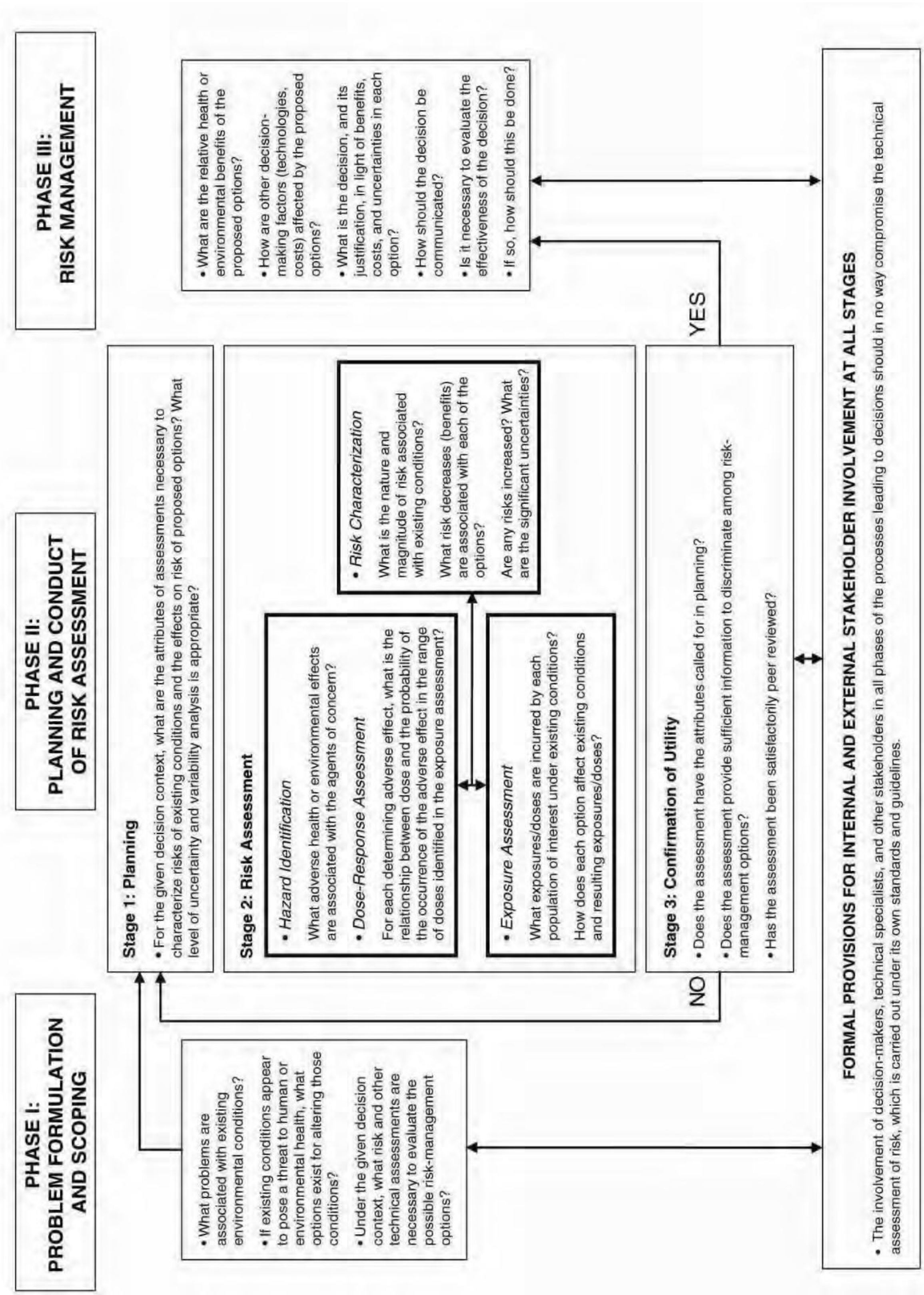

Figure 1. A Framework for Risk-Based Decision-Making that Maximizes the Utility of Risk Assessment. [NRC 2009, p11]