

RISK CHARACTERIZATION: PRINCIPLES AND PRACTICE

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In the field of risk assessment, characterizing the nature and magnitude of human health or environmental risks is arguably the most important step in the analytical process. In this step, data on the dose-response relationship of an agent are integrated with estimates of the degree of exposure in a population to characterize the likelihood and severity of risk. Although the purpose of risk characterizations is to make sense of the available data and describe what they mean to a broad audience, this step is often given insufficient attention in health risk evaluations. Too often, characterizations fail to interpret or summarize risk information in a meaningful way, or they present single numerical estimates of risk without an adequate discussion of the uncertainties inherent in key exposure parameters or the dose-response assessment, model assumptions, or analytical limitations. Consequently, many users of risk information have misinterpreted the findings of a risk assessment or have false impressions about the degree of accuracy (or the confidence of the scientist) in reported risk estimates. In this article we collected and integrated the published literature on conducting and reporting risk characterizations to provide a broad, yet comprehensive, analysis of the risk characterization process as practiced in the United States and some other countries. Specifically, the following eight topics are addressed: (1) objective of risk characterization, (2) guidance documents on risk characterization, (3) key components of risk characterizations, (4) toxicity criteria for evaluating health risks, (5) descriptors used to characterize health risks, (6) methods for quantifying human health risks, (7) key uncertainties in risk characterizations, and (8) the risk decision-making process. A brief discussion is also provided on international aspects of risk characterization. A number of examples are presented that illustrate key concepts, and citations are provided for approximately 100 of the most relevant papers.